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Selected Federal Health Insurance Provisions

Volume I

Requirements Relating to Health Care Access

45 C.F.R. Parts 144 – 153

This is an unofficial compilation of selected Department of Health and Human Services ("HHS") regulations affecting health insurers codified in Title 45 Code of Federal Regulations Parts 144 through 153.

For Volume II, which includes 45 C.F.R. Parts 154-159, click here and see the last item under "Compiled Rules."

Note: Although reasonable effort has been made to compile these provisions as published by HHS, no assurance can be given that this compilation is a completely accurate restatement of the Federal health insurance provisions.

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CODE OF FEDERAL REGULATIONS TITLE 45—PUBLIC WELFARE AND HUMAN SERVICES

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

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

SUBPART A—GENERAL PROVISIONS

§ 144.101 Basis and purpose.

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

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

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

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

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

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

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

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

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

§ 144.102 Scope and applicability.

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

(b) The protections afforded under 45 CFR parts 144 through 149 to individuals and employers (and other sponsors of health insurance offered in connection with a group health plan) are determined by whether the coverage involved is obtained in the small group market, the large group market, or the individual market.

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

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

§ 144.103 Definitions.

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

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

Applicable State authority means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of 45 C.F.R. 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 C.F.R. § 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 C.F.R. part 146, subpart E, is defined in 45 C.F.R. § 146.150(b); and

(2) The individual market provisions in 45 C.F.R. part 148, is defined in 45 C.F.R. § 148.103.

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

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

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

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

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

Excepted benefits, consistent for purposes of the—

(1) Group market provisions in 45 C.F.R. part 146 subpart D, is defined in 45 C.F.R. § 146.145(b); and

(2) Individual market provisions in 45 C.F.R. part 148, is defined in 45 C.F.R. § 148.220.

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

First day of coverage means, in the case of an individual covered for benefits under a group health plan, the first day of coverage under the plan and, in

the case of an individual covered by health insurance coverage in the individual market, the first day of coverage under the policy or contract.

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

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

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

Group health plan or *plan* means a group health plan within the meaning of 45 C.F.R. § 146.145(a).

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

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

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

Health maintenance organization or *HMO* means—

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

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

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

Health status-related factor is any factor identified as a health factor in 45 C.F.R. § 146.121(a).

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

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

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

Issuer means a *health insurance issuer.*

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

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

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

Late enrollment means enrollment of an individual under a group health plan other than on the earliest

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

Medical care means amounts paid for—

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

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

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

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

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

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

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

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

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

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

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

(i) Has the same cost-sharing structure as before the modification, or any variation in cost sharing is solely related to changes in cost or utilization of medical care, or is to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act;

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

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

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

(i) The modification is made within a reasonable time period after the imposition or

modification of the Federal or State requirement;

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

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

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

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

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

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

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

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

Policy year means, with respect to—

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

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

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

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

Public health plan has the meaning given the term in 45 C.F.R. § 146.113(a)(1)(ix).

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration of no longer than 36 months in total;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 1, excluding the heading "Notice 1," with any additional information required by applicable state law:

Notice 1:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage. Also, this coverage is not "minimum essential coverage." If you don't have minimum essential coverage for any month in 2018, you may have to make a payment when you file your tax return unless you qualify for an exemption from the requirement that you have health coverage for that month.

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the language in the following Notice 2, excluding the heading "Notice 2," with any additional information required by applicable state law:

Notice 2:

This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage.

(4) If a court holds the 36-month maximum duration provision set forth in paragraph (1) of this definition or its applicability to any person or circumstances invalid, the remaining provisions and their applicability to other people or circumstances shall continue in effect.

Significant break in coverage has the meaning given the term in 45 C.F.R. § 146.113(b)(2)(iii).

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

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

Special enrollment means enrollment in a group health plan or group health insurance coverage under the rights described in 45 C.F.R. § 146.117.

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

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

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

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

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

SUBPART B—QUALIFIED STATE LONG-TERM CARE INSURANCE PARTNERSHIPS: REPORTING REQUIREMENTS FOR INSURERS

[*Not included in this compilation*]

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

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).

SUBPART A—GENERAL PROVISIONS

§ 146.101 Basis and scope.

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

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

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

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

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

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

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

SUBPART B—REQUIREMENTS RELATING TO ACCESS AND RENEWABILITY OF COVERAGE, AND LIMITATIONS ON PREEXISTING CONDITION EXCLUSION PERIODS

§ 146.111 Preexisting condition exclusions.

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

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

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

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

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

(ii) *Conclusion.* In this *Example 2*, the plan provision excluding cosmetic surgery benefits for individuals injured before enrolling in the plan is a preexisting condition exclusion because it operates to exclude benefits relating to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is prohibited.

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 146.113 – 146.119 ***[****Not included in this compilation. Rules related to creditable coverage, certification of previous coverage, etc..****]***

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

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

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

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

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

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

(ii) *Conclusion.* In this *Example 1*, the limit does not violate this paragraph (b)(2)(i) because coverage of the specific, nonessential health benefit up to $10,000 is available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to

all participants and beneficiaries and is not directed at individual participants or beneficiaries.

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

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

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual *C* is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about *C's* adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that *C* has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for *C* for that condition. The exclusionary rider is made effective the first day of the next plan year.

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

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

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

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

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

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

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

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

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

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

program that satisfies the requirements of paragraph (f) of this section.

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

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

Example 1. (i) *Facts.* A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or injuries sustained in connection with attempted suicide. Because of depression, Individual *D* attempts suicide. As a result, *D* sustains injuries and is hospitalized for treatment of the injuries. Under the exclusion, the plan denies *D* benefits for treatment of the injuries.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) Marital status;

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

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

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

(3) *Discrimination directed at individuals.* Notwithstanding paragraphs (d)(1) and (d)(2) of this section, if the creation or modification of an employment or coverage classification is directed

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

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

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

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

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

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

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

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

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

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

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

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

(e) *Nonconfinement and actively-at-work provisions*—(1) *Nonconfinement provisions*—(i) *General rule.* Under the rules of paragraphs (b) and

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

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

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

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

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

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

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

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

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

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

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

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

(ii) *Exception for the first day of work*—(A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan or issuer may establish a rule for eligibility that requires an

individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(F) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as

part of the assessment. (*See also* § 146.122 for rules prohibiting collection of genetic information.)

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

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

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

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

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

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

(ii) *Size of reward.* The reward for the activity-only wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children)

may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

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

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

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

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

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

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

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

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

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

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

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

furnished pursuant to the physician's recommendations.

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

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

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

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

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

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

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

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

(ii) *Size of reward.* The reward for the outcome-based wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage

under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(4)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To ensure that an outcome-based wellness program is reasonably designed to improve health and does not act as a subterfuge for underwriting or reducing benefits based on a health factor, a reasonable alternative standard to qualify for the reward must be provided to any individual who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor, as explained in paragraph (f)(4)(iv) of this section.

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

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

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

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

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

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

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

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

furnished pursuant to the physician's recommendations.

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

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

(*2*) An individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan or issuer, but only if the physician joins in the request. The individual can make a request to involve a personal physician's recommendations at any time and the personal physician can adjust the physician's recommendations at any time, consistent with medical appropriateness.

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

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an outcome-based wellness program, and in any disclosure that an individual did not satisfy an initial outcome-based standard, the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that

recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

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

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

(ii) *Conclusion.* In this *Example 1,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain cholesterol level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because the cholesterol program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all participants who do not meet the cholesterol standard a reasonable alternative standard to qualify for the reward. Lastly, the plan also discloses in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard the availability of a reasonable alternative standard (including contact information and the individual's ability to involve his or her personal physician), as required by paragraph (f)(4)(v) of this section. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

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

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

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

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

Example 4—BMI screening with walking program alternative. (i) *Facts.* A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is

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

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

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

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

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

(ii) *Conclusion.* In this *Example 6*, the premium differential satisfies the requirements of paragraphs

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

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

(ii) *Conclusion.* In this *Example 7*, the program is not reasonably designed under paragraph (f)(4)(iii) of this section and does not provide a reasonable alternative standard as required under paragraph (f)(4)(iv) of this section. The plan cannot cease to provide a reasonable alternative standard merely because the participant did not stop smoking after participating in a smoking cessation program. The plan must continue to offer a reasonable alternative standard whether it is the same or different (such as a new recommendation from *F*'s personal physician or a new nicotine replacement therapy).

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

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

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

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

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

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

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

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

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

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

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

wellness program, with an opportunity to earn a $1,500 reward.

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

(6) *Sample language.* The following language, or substantially similar language, can be used to satisfy the notice requirement of paragraphs (f)(3)(v) or (f)(4)(v) of this section: "Your health plan is committed to helping you achieve your best health. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you (and, if you wish, with your doctor) to find a wellness program with the same reward that is right for you in light of your health status."

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

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

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

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

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

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

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

(ii) *Conclusion.* In this *Example 3*, the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for

COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)

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

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

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

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

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

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

(2) *Special rule for self-funded nonfederal governmental plans exempted under 45 C.F.R. § 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.)

§ 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['s]* group health plan covers genetic testing for celiac disease for individuals

who have family members with this condition. After *A's* son is diagnosed with celiac disease, *A* undergoes a genetic test and promptly submits a claim for the test to *A's* issuer for reimbursement. The issuer asks *A* to provide the results of the genetic test before the claim is paid.

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

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

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

Example 3. (i) *Facts*. Individual *C* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *C's* physician, *C* has been taking a regular dose of tamoxifen to help prevent a recurrence. *C's* group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion*. In this *Example 3*, the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on *C's* undergoing a genetic test to determine what genetic markers *C* has for making the CYP2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *C*.

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

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

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

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

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

(ii) *Conclusion*. In this *Example 6*, because the enhanced benefits include benefits not related to the

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

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

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

(a) *Scope.* This section applies to health reimbursement arrangements (HRAs) and other account-based group health plans, as defined in § 147.126(d)(6)(i) of this subchapter. For ease of reference, the term "HRA" is used in this section to include other account-based group health plans. For related regulations, see 26 CFR 1.36B– 2(c)(3)(i) and (c)(5), 29 CFR 2510.3–1(l), and 45 CFR 155.420.

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

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

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

(ii) *Forfeiture.* The HRA must provide that if any individual covered by the HRA ceases to be covered by individual health insurance coverage, the HRA will not reimburse medical care expenses that are incurred by that individual after the individual health insurance coverage ceases. In addition, if the participant and all dependents covered by the participant's HRA cease to be covered by individual health insurance coverage, the participant must forfeit the HRA. In either

case, the HRA must reimburse medical care expenses incurred by the individual prior to the cessation of individual health insurance coverage to the extent the medical care expenses are otherwise covered by the HRA, but the HRA may limit the period to submit medical care expenses for reimbursement to a reasonable specified time period. If a participant or dependent loses coverage under the HRA for a reason other than cessation of individual health insurance coverage, COBRA and other continuation coverage requirements may apply.

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

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

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

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

disregarded for purposes of determining whether the HRA is offered on the same terms, provided that if the HRA makes available transferred amounts, it does so on the same terms for all participants in the class of employees.

(iii) *Permitted variation.* An HRA does not fail to be provided on the same terms solely because the maximum dollar amount made available to participants in a class of employees to reimburse medical care expenses for any plan year increases in accordance with paragraph (c)(3)(iii)(A) or (B) of this section.

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

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

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

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

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

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

dependents covered by the HRA on the first day of the plan year or is pro-rated for the remainder of the plan year after the change in the number of the participant's dependents covered by the HRA consistent with the portion of the plan year in which that number of dependents are covered by the HRA. The method the HRA uses to determine amounts made available for participants whose coverage under the HRA is effective later than the first day of the plan year or who have changes in the number of dependents covered by the HRA during a plan year must be the same for all participants in the class of employees and the method must be determined prior to the beginning of the plan year.

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

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

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

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

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

(*2*) *Conclusion.* The same terms requirement of this paragraph (c)(3) is satisfied in this paragraph (c)(3)(vii)(B) (*Example 2*) for 2020 because Plan Sponsor B offers all employees employed

on the first day of the plan year the same amount, $7,000, in an HRA for that plan year and all employees hired after January 1, 2020, a pro-rata amount based on the portion of the plan year during which they are enrolled in the HRA.

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

(*2*) *Conclusion.* The same terms requirement of this paragraph (c)(3) is satisfied in this paragraph (c)(3)(vii)(C) (*Example 3*) because paragraph (c)(3)(iii)(A) of this section allows the maximum dollar amount made available in an HRA to increase as the number of the participant's dependents covered by the HRA increases and Plan Sponsor C makes the same amount available to each employee with the same number of dependents covered by the HRA.

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

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

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

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

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

(5) *Reasonable procedures for coverage substantiation*—(i) *Substantiation of individual health insurance coverage for the plan year.* The HRA must implement, and comply with, reasonable procedures to substantiate that participants and each dependent covered by the HRA are, or will be, enrolled in individual health insurance coverage for the plan year (or for the portion of the plan year the individual is covered by the HRA, if applicable). The HRA may establish the date by which this substantiation must be provided, but, in general, the date may be no later than the first day of the plan year. However, for a participant who is not eligible to participate in the HRA on the first day of the plan year (or who becomes eligible fewer than 90 days prior to the plan year or for whom the notice under paragraph (c)(6) of this section is required to be provided as set forth in paragraph (c)(6)(i)(C) of this section), the HRA may establish the date by which this substantiation must be provided, but that date may be no later than the date the HRA coverage begins. Similarly, for a participant who adds a new dependent during the plan year, the HRA may establish the date by which this substantiation must be provided, but the date may be no later than the date the HRA coverage for the new dependent begins; however, to the extent the dependent's coverage under the HRA is effective retroactively, the HRA may establish a reasonable time by which this substantiation is required, but must require it be provided before the HRA will reimburse any medical care expense for the newly added dependent. The reasonable procedures an HRA may use to implement the substantiation requirement set forth in this paragraph (c)(5)(i) may include a requirement that a participant substantiate enrollment by providing either:

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

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

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

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

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

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

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

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

(ii) *Content.* The notice must include all the information described in this paragraph (c)(6)(ii) (and may include any additional information that does not conflict with that information). To the extent that the Departments of the Treasury, Labor and Health and Human Services provide model notice language for certain elements of this required notice, HRAs are permitted, but not required, to use the model language.

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

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

(C) A description of the potential availability of the premium tax credit if the participant opts out of and waives future reimbursements from the HRA and the HRA is not affordable for one or more months under 26 CFR 1.36B– 2(c)(5), a statement that even if the participant opts out of and waives future reimbursements from an HRA, the offer will prohibit the participant (and, potentially, the participant's dependents) from receiving a premium tax credit for the participant's coverage (or the dependent's coverage, if applicable) on an Exchange for any month that the HRA is affordable under 26 CFR 1.36B–2(c)(5), a statement describing how the participant may find assistance with determining affordability, a statement that, if the participant is a former employee, the offer of the HRA does not render the participant (or the participant's dependents, if applicable) ineligible for the

premium tax credit regardless of whether it is affordable under 26 CFR 1.36B–2(c)(5), and a statement that if the participant or dependent is enrolled in Medicare, he or she is ineligible for the premium tax credit without regard to the offer or acceptance of the HRA;

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

(E) A statement that the participant must inform any Exchange to which the participant applies for advance payments of the premium tax credit of the availability of the HRA; the self-only HRA amount available for the HRA plan year (or the maximum dollar amount available for the plan year if the HRA provides for reimbursements up to a single dollar amount regardless of whether a participant has self-only or other than self-only coverage) as set forth in the written notice in accordance with paragraph (c)(6)(ii)(A) of this section; whether the HRA is also available to the participant's dependents and if so, which ones; the date as of which coverage under the HRA may first become effective; the date on which the plan year begins and the date on which it ends; and whether the participant is a current employee or former employee.

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

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

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

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

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

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

414(b), (c), (m), and (o) of the Code that would treat the common law employer as a single employer with certain other entities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

offers an individual coverage HRA to one or more other classes of employees.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

purposes of determining the applicable class size minimum under paragraph (d)(3)(iii) of this section. If a student employee is not offered a student premium reduction arrangement (including if the student employee is offered an individual coverage HRA instead), the student employee is considered to be part of the class of employees to which the employee otherwise belongs and is counted for purposes of determining the applicable class size minimum under paragraph (d)(3)(iii) of this section.

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

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

(ii) *Exceptions.* For purposes of the statement regarding ERISA under the notice content element under paragraph (c)(6)(ii)(A) of this section and the statement regarding the availability of a special enrollment period under the notice content element under paragraph (c)(6)(ii)(J) of this section, the term individual health insurance coverage means only individual health insurance coverage and does not also mean coverage under Medicare Part A and B or Part C.

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

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

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

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

the same terms (as required by the collective bargaining agreement).

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

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

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

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

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

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

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

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

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(1)(vi) (*Example 6*) because, even though the employees who are temporarily placed with customers generally may be treated as employees of a different class, because Plan Sponsor E is also using a rating area to identify the class offered the HRA (which is an applicable class for the minimum class size requirement) and is offering one class the HRA and another class the traditional group health plan, the minimum class size requirement applies to the class offered the HRA, and the class offered the HRA fails to satisfy the minimum class size requirement. Because Plan Sponsor E employs 210 employees, the applicable class size minimum is 20, and the HRA is offered to only 10 employees.

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

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

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

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

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

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(ix) (*Example 9*) because employees whose work sites are in different rating areas may be considered different classes and Plan Sponsor H offers the HRA on the same terms to all full-time employees in rating area 2. The minimum class size requirement applies to the class offered the HRA in this paragraph (f)(1)(ix) (*Example 9*) because the minimum class size requirement applies to a class based on a geographic area unless the geographic area is a state or a combination of two or more entire states. However, the minimum class size requirement applies only to the class offered the HRA, and Plan Sponsor H offers the HRA to the 552 full-time employees in rating area 2 on the first day of the plan year, satisfying the minimum class size requirement (because the applicable class size minimum for Plan Sponsor H is 20).

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

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

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

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(xi) (*Example 11*). Plan

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

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

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(1)(xii) (*Example 12*) because, even though salaried and hourly employees generally may be considered different classes and Plan Sponsor J offers the HRA on the same terms to all hourly employees, the HRA fails to satisfy the minimum class size requirement. Specifically, the minimum class size requirement applies in this paragraph (f)(1)(xii) (*Example 12*) because employees who are paid on a salaried basis and employees who are not paid on a salaried basis are applicable classes subject to the minimum class size requirement. Because Plan Sponsor J reasonably expects to employ between 100 and 200 employees on the first day of the plan year, the applicable class size minimum is 10 percent, rounded down to a whole number. Ten percent of 177 total employees, rounded down to a whole number is 17, and the HRA is offered to only 14 hourly employees.

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

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

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

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

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

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

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

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(xvi) (*Example 16*) because full-time employees and part-time employees may be treated as different classes, Plan Sponsor L offers an HRA on the same terms to all the participants in the part-time class, and the minimum class size requirement is satisfied. Specifically, whether a class of employees satisfies the applicable class size minimum is determined as of the first day of the plan year based on the number of employees in a class that is offered an HRA, not on the number of employees who enroll in the HRA. The applicable class size minimum for Plan Sponsor L is 10 employees, and Plan Sponsor L offered the HRA to its 12 part-time employees.

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

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

(xiii (*sic—should be* xviii)) *Example 18: Student employees offered student premium reduction arrangements and minimum class size requirement*—(A) *Facts.* Plan Sponsor N is an institution of higher education with 25 hourly employees. Plan Sponsor N offers 15 of its hourly employees, who are student employees, a student premium reduction arrangement and it wants to offer its other 10

hourly employees an HRA for 2022. Plan Sponsor N offers its salaried employees a traditional group health plan. Plan Sponsor N reasonably expects to have 250 employees on the first day of the 2022 HRA plan year, 15 of which will have offers of student premium reduction arrangements.

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

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

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

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

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

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

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

plan to its full-time employees hired before January 1, 2023.

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

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

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

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

(B) *Conclusion.* Plan Sponsor D may not apply the special rule for new hires for 2030 to the class of full-time employees being offered an HRA because the special rule for new hires may only be applied to a class that is being offered a traditional group health plan.

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

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

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

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

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

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(2)(viii) (*Example 8*) because even though the new hire subclass has been subdivided, it has been subdivided in a manner that is not subject to the minimum class size requirement as the subdivision is based on the entire state.

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

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

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

§ 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 C.F.R. parts 144 and 146, contained in the 45 C.F.R., parts 1 to 199, edition revised as of October 1, 2004. Notwithstanding the previous sentence, the definition of "short-term, limited-duration insurance" in § 144.103 of this subchapter applies October 2, 2018.

SUBPART C—REQUIREMENTS RELATED TO BENEFITS

§ 146.130 Standards relating to benefits for mothers and newborns *[Not included in this compilation.]*

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

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

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

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

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

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

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

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

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the plan or coverage as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any condition defined by the plan or coverage as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment.

Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits.* This paragraph (b) details the application of the parity requirements with respect to aggregate lifetime and annual dollar limits. This paragraph (b) does not address the provisions of PHS Act section 2711, which prohibit imposing lifetime and annual limits on the dollar value of essential health benefits. For more information, see § 147.126 of this subchapter.

(1) *General*—(i) *General parity requirement.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/ surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(5) of this section.

(ii) *Exception.* The rule in paragraph (b)(1)(i) of this section does not apply if a plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(2) *Plan with no limit or limits on less than one-third of all medical/surgical benefits.* If a plan (or health insurance coverage) does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) *Plan with a limit on at least two-thirds of all medical/surgical benefits.* If a plan (or health insurance coverage) includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

i) Apply the aggregate lifetime or annual dollar limit both to the medical/ surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/ surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)

(4) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this paragraph (b), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

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

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

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance

use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(5)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(ii) *Weighting.* For purposes of this paragraph (b)(5), the weighting applicable to any category of medical/ surgical benefits is determined in the manner set forth in paragraph (b)(4) of this section for determining one-third or two-thirds of all medical/surgical benefits.

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

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

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

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

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

(ii) *Classifications of benefits used for applying rules*—(A) *In general.* If a plan (or

health insurance coverage) provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c):

(*1*) *Inpatient, in-network.* Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage. See special rules for plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*2*) *Inpatient, out-of-network.* Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(*3*) *Outpatient, in-network.* Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage. See special rules for office visits and plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*4*) *Outpatient, out-of-network.* Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers. See special rules for office visits in paragraph (c)(3)(iii) of this section.

(*5*) *Emergency care.* Benefits for emergency care.

(*6*) *Prescription drugs.* Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

(B) *Application to out-of-network providers.* See paragraph (c)(2)(ii)(A) of this section, under which a plan (or health insurance coverage) that provides mental health or substance use disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 1*, because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and

treatment limitations, including the deductible, in each classification.

Example 2. (i) *Facts.* A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 2*, because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

Example 3. (i) *Facts.* Same facts as *Example 2*, except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 3*, because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for—

(A) Benefits in the emergency care classification; and

(B) All other benefits.

Example 4. (i) *Facts.* Same facts as *Example 2*, except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this *Example 4*, because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for—

(A) Inpatient, out-of-network benefits; and

(B) All other benefits.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining "substantially all" and "predominant"*—(A) *Substantially all.* For purposes of this paragraph (c), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/ surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant*—(*1*) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(*2*) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the

combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on plan payments.* For purposes of this paragraph (c), the determination of the portion of medical/ surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707(b) and Affordable Care Act section 1302(c), which establish limitations on annual deductibles for non-grandfathered health plans in the small group market and annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

(E) *Determining the dollar amount of plan payments.* Subject to paragraph (c)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/ surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) *Application to different coverage units.* If a plan (or health insurance coverage) applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(iii) *Special rules*—(A) *Multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/ surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any

financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

(C) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (c), a plan or issuer may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(3)(iii)(C). After the sub-classifications are established, the plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(3)(iii)(C) are:

(*1*) Office visits (such as physician visits), and

(*2*) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

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

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

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

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

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

Example 2. (i) *Facts.* For outpatient, in-network medical/surgical benefits, a plan imposes five different

copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

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

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

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

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

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

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

Tier 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).

Example 5. (i) *Facts.* A plan has two-tiers of network of providers: A preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/ participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/ surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 5*, the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

Example 6. (i) *Facts.* With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 6*, the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

Example 7. (i) *Facts.* Same facts as *Example 6*, but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(ii) *Conclusion.* In this *Example 7*, the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

(v) *No separate cumulative financial requirements or cumulative quantitative treatment limitations*—(A) A group health plan (or health insurance coverage offered in connection with a group health plan) may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification. (B) The rules of this paragraph (c)(3)(v) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a combined annual $500 deductible on all medical/surgical, mental health, and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 1*, the combined annual deductible complies with the requirements of this paragraph (c)(3)(v).

Example 2. (i) *Facts.* A plan imposes an annual $250 deductible on all medical/ surgical benefits and a separate annual $250 deductible on all mental health and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 2*, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 3. (i) *Facts.* A plan imposes an annual $300 deductible on all medical/ surgical benefits and a separate annual $100 deductible on all mental health or substance use disorder benefits.

(ii) *Conclusion.* In this *Example 3*, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 4. (i) *Facts.* A plan generally imposes a combined annual $500 deductible on all benefits (both medical/surgical benefits and mental health and substance use disorder benefits) except prescription drugs. Certain benefits, such as preventive care, are provided without regard to the deductible. The imposition of other types of financial requirements or treatment limitations varies with each classification. Using reasonable methods, the plan projects its payments for medical/surgical benefits in each classification for the upcoming year as follows:

Classification	Benefits subject to deductible	Total benefits	Percent subject to deductible
Inpatient, in-network	$1,800x	$2,000x	90
Inpatient, out-of-network	1,000x	1,000x	100
Outpatient, in-network	1,400x	2,000x	70
Outpatient, out-of-network	1,880x	2,000x	94
Emergency care	300x	500x	60

(ii) *Conclusion.* In this *Example 4*, the two-thirds threshold of the substantially all standard is met with respect to each classification except emergency care because in each of those other classifications at least two-thirds of medical/surgical benefits are subject to the $500 deductible. Moreover, the $500 deductible is the predominant level in each of those other classifications because it is the only level. However, emergency care mental health and substance use disorder benefits cannot be subject to the $500 deductible because it does not apply to substantially all emergency care medical/ surgical benefits.

(4) *Nonquantitative treatment limitations*—(i) *General rule.* A group health plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder

benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

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

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

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iii) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* A plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient mental health and substance use disorder benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for seven days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. On the other hand, for inpatient mental health and substance use disorder benefits, routine approval is given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan.

(ii) *Conclusion.* In this Example 1, the plan violates the rules of this paragraph (c)(4) because it is applying a stricter nonquantitative treatment limitation in practice to mental health and substance use disorder benefits than is applied to medical/ surgical benefits.

Example 2. (i) *Facts.* A plan applies concurrent review to inpatient care where there are high levels of variation in length of stay (as measured by a coefficient of variation exceeding 0.8). In practice, the application of this standard affects 60 percent of mental health conditions and substance use disorders, but only 30 percent of medical/ surgical conditions.

(ii) *Conclusion.* In this *Example 2,* the plan complies with the rules of this paragraph (c)(4) because the evidentiary standard used by the plan is applied no more stringently for mental health and substance use disorder benefits than for medical/surgical benefits, even though it results in an overall difference in the application of concurrent review for mental health conditions or substance use disorders than for medical/surgical conditions.

Example 3. (i) *Facts.* A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits and uses comparable criteria in determining whether a course of treatment is medically necessary. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.

(ii) *Conclusion.* In this *Example 3*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical necessity—is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, it is not applied in a comparable way. The penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/ surgical benefits.

Example 4. (i) *Facts.* A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition.

(ii) *Conclusion.* In this *Example 4*, the plan complies with the rules of this paragraph (c)(4) because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.

Example 5. (i) *Facts.* A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects). For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 5*, the plan violates the rules of this paragraph (c)(4). Although the standard for applying a nonquantitative treatment limitation is the same for both mental health and substance use disorder benefits and medical/surgical benefits—whether a drug has a black box warning—it is not applied in a comparable manner. The plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 6. (i) *Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(ii) *Conclusion.* In this *Example 6*, limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

Example 7. (i) *Facts.* Training and State licensing requirements often vary among types of providers. A plan applies a general standard that any provider must meet the highest licensing requirement related to supervised clinical experience under applicable State law in order to participate in the plan's provider network. Therefore, the plan requires master's-level mental health therapists to have post-degree, supervised clinical experience but does not impose this requirement on master's-level general medical providers because the scope of their licensure under applicable State law does require clinical experience. In addition, the plan does not require post-degree, supervised clinical experience for psychiatrists or Ph.D. level psychologists since their licensing already requires supervised training.

(ii) *Conclusion.* In this *Example 7*, the plan complies with the rules of this paragraph (c)(4). The requirement that master's-level mental health therapists must have supervised clinical experience to join the network is permissible, as long as the plan consistently applies the same standard to all providers even though it may have a disparate impact on certain mental health providers.

Example 8. (i) *Facts.* A plan considers a wide array of factors in designing medical management techniques for both mental health and substance use disorder benefits and medical/surgical benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud. Based on application of these factors in a comparable fashion, prior authorization is required for some (but not

all) mental health and substance use disorder benefits, as well as for some medical/surgical benefits, but not for others. For example, the plan requires prior authorization for: Outpatient surgery; speech, occupational, physical, cognitive and behavioral therapy extending for more than six months; durable medical equipment; diagnostic imaging; skilled nursing visits; home infusion therapy; coordinated home care; pain management; high-risk prenatal care; delivery by cesarean section; mastectomy; prostate cancer treatment; narcotics prescribed for more than seven days; and all inpatient services beyond 30 days. The evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by the plan.

(ii) *Conclusion.* In this *Example 8*, the plan complies with the rules of this paragraph (c)(4). Under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those applied with respect to medical/surgical benefits.

Example 9. (i) *Facts.* A plan generally covers medically appropriate treatments. The plan automatically excludes coverage for inpatient substance use disorder treatment in any setting outside of a hospital (such as a freestanding or residential treatment center). For inpatient treatment outside of a hospital for other conditions (including freestanding or residential treatment centers prescribed for mental health conditions, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the inpatient treatment is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 9*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of substance use disorder treatment in any setting outside of a hospital is not comparable to the conditional exclusion of inpatient treatment outside of a hospital for other conditions.

Example 10. (i) *Facts.* A plan generally provides coverage for medically appropriate medical/surgical benefits as well as mental health and substance use disorder benefits. The plan excludes coverage for inpatient, out-of-network treatment of chemical dependency when obtained outside of the State where the policy is written. There is no similar exclusion for medical/surgical benefits within the same classification.

(ii) *Conclusion.* In this Example 10, the plan violates the rules of this paragraph (c)(4). The plan is imposing a nonquantitative treatment limitation that restricts benefits based on geographic location. Because there is no comparable exclusion that applies to medical/surgical benefits, this exclusion may not be applied to mental health or substance use disorder benefits.

Example 11. (i) *Facts.* A plan requires prior authorization for all outpatient mental health and substance use disorder services after the ninth visit and will only approve up to five additional visits per authorization. With respect to outpatient medical/surgical benefits, the plan allows an initial visit without prior authorization. After the initial visit, the plan pre-approves benefits based on the individual treatment plan recommended by the attending provider based on that individual's specific medical condition. There is no explicit, predetermined cap on the amount of additional visits approved per authorization.

(ii) *Conclusion.* In this *Example 11*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—prior authorization to determine medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way. While the plan is more generous with respect to the number of visits initially provided without preauthorization for mental health benefits, treating all mental health conditions and substance use disorders in the same manner, while providing for individualized treatment of medical conditions, is not a comparable application of this nonquantitative treatment limitation.

(5) *Exemptions.* The rules of this paragraph (c) do not apply if a group health plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(d) *Availability of plan information*—(1) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request.

(2) *Reason for any denial.* The reason for any denial under a group health plan (or health insurance coverage offered in connection with such plan) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary. For this purpose, a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) that provides the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503–1 for group health plans complies with the requirements of this paragraph (d)(2).

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (d)(2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, § 147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/ surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/ surgical benefits and mental health or substance use disorder benefits under the plan.

(e) *Applicability*—(1) *Group health plans.* The requirements of this section apply to a group health plan offering medical/surgical benefits and mental health or substance use disorder benefits. If, under an arrangement or arrangements to provide medical care benefits by an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans), any participant (or beneficiary) can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section (including the exemption provisions in paragraph (g) of this section) apply separately with respect to each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any participant (or beneficiary) can simultaneously receive from that employer's or employee organization's arrangement or arrangements to provide medical care benefits, and all such combinations are considered for purposes of this section to be a single group health plan.

(2) *Health insurance issuers.* The requirements of this section apply to a health insurance issuer offering health insurance coverage for mental health or substance use disorder benefits in connection with a group health plan subject to paragraph (e)(1) of this section.

(3) *Scope.* This section does not—

(i) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a plan (or health insurance coverage) for one or more mental health conditions or substance use disorders does not require the plan or health insurance coverage under this section to provide benefits for any other mental health condition or substance use disorder;

(ii) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides coverage for mental health or substance use disorder benefits only to the extent required under PHS Act section 2713 to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(iii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the plan (or health insurance coverage) except as specifically provided in paragraphs (b) and (c) of this section.

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section changes the requirements of §§ 147.150 and 156.115 of this subchapter, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under §§ 156.110(a)(5) and 156.115(a) of this subchapter, must comply with the provisions of this section to satisfy the requirement to provide essential health benefits.

(f) *Small employer exemption*—(1) *In general.* The requirements of this section do not apply to a group health plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer (as defined in section 2791 of the PHS Act).

(2) *Rules in determining employer size.* For purposes of paragraph (f)(1) of this section—

(i) All persons treated as a single employer under subsections (b), (c), (m), and (o) of section 414 of the Internal Revenue Code are treated as one employer;

(ii) If an employer was not in existence throughout the preceding calendar year, whether it is a small employer is determined based on the average number of employees the employer reasonably expects to employ on business days during the current calendar year; and

(iii) Any reference to an employer for purposes of the small employer exemption includes a reference to a predecessor of the employer.

(g) *Increased cost exemption*—(1) *In general.* If the application of this section to a group health plan (or health insurance coverage offered in connection with such plans) results in an increase for the plan year involved of the actual total cost of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits as determined and certified under paragraph (g)(3) of this section by an amount that exceeds the applicable percentage described in paragraph (g)(2) of this section of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for one plan year. An employer or issuer may elect to continue to provide mental health and substance use disorder benefits in compliance with this section with respect to the plan or coverage involved regardless of any increase in total costs.

(2) *Applicable percentage.* With respect to a plan or coverage, the applicable percentage described in this paragraph (g) is—

(i) 2 percent in the case of the first plan year in which this section is applied to the plan or coverage; and

(ii) 1 percent in the case of each subsequent plan year.

(3) *Determinations by actuaries*—(i) Determinations as to increases in actual costs under a plan or coverage that are attributable to implementation of the requirements of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations must be based on the formula specified in paragraph (g)(4) of this section and shall be in a written report prepared by the actuary.

(ii) The written report described in paragraph (g)(3)(i) of this section shall be maintained by the group health plan or health insurance issuer, along with all supporting documentation relied upon by the actuary, for a period of six years following the notification made under paragraph (g)(6) of this section.

(4) *Formula.* The formula to be used to make the determination under paragraph (g)(3)(i) of this section is expressed mathematically as follows: $[(E1 - E0)/T0] - D > k$

(i) E1 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the base period, including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these

benefits consistent with the requirements of this section.

(ii) E0 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the length of time immediately before the base period (and that is equal in length to the base period), including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits.

(iii) T0 is the actual total cost of coverage with respect to all benefits during the base period.

(iv) k is the applicable percentage of increased cost specified in paragraph (g)(2) of this section that will be expressed as a fraction for purposes of this formula.

(v) D is the average change in spending that is calculated by applying the formula *(E1 - E0)/T0* to mental health and substance use disorder spending in each of the five prior years and then calculating the average change in spending.

(5) *Six month determination.* If a group health plan or health insurance issuer seeks an exemption under this paragraph (g), determinations under paragraph (g)(3) of this section shall be made after such plan or coverage has complied with this section for at least the first 6 months of the plan year involved.

(6) *Notification.* A group health plan or health insurance issuer that, based on the certification described under paragraph (g)(3) of this section, qualifies for an exemption under this paragraph (g), and elects to implement the exemption, must notify participants and beneficiaries covered under the plan, the Secretary, and the appropriate State agencies of such election.

(i) *Participants and beneficiaries*—(A) *Content of notice.* The notice to participants and beneficiaries must include the following information:

(*1*) A statement that the plan or issuer is exempt from the requirements of this section and a description of the basis for the exemption.

(*2*) The name and telephone number of the individual to contact for further information.

(*3*) The plan or issuer name and plan number (PN).

(*4*) The plan administrator's name, address, and telephone number.

(*5*) For single-employer plans, the plan sponsor's name, address, and telephone number (if different from paragraph (g)(6)(i)(A)(*3*) of this section) and the plan sponsor's employer identification number (EIN).

(*6*) The effective date of such exemption.

(*7*) A statement regarding the ability of participants and beneficiaries to contact the plan administrator or health insurance issuer to see how benefits may be affected as a result of the plan's or issuer's election of the exemption.

(*8*) A statement regarding the availability, upon request and free of charge, of a summary of the information on which the exemption is based (as required under paragraph (g)(6)(i)(D) of this section).

(B) *Use of summary of material reductions in covered services or benefits.* A plan or issuer may satisfy the requirements of paragraph (g)(6)(i)(A) of this section by providing participants and beneficiaries (in accordance with paragraph (g)(6)(i)(C) of this section) with a summary of material reductions in covered services or benefits consistent with 29 CFR 2520.104b–3(d) that also includes the information specified in paragraph (g)(6)(i)(A) of this section. However, in all cases, the exemption is not

effective until 30 days after notice has been sent.

(C) *Delivery.* The notice described in this paragraph (g)(6)(i) is required to be provided to all participants and beneficiaries. The notice may be furnished by any method of delivery that satisfies the requirements of section 104(b)(1) of ERISA (29 U.S.C. 1024(b)(1)) and its implementing regulations (for example, first-class mail). If the notice is provided to the participant and any beneficiaries at the participant's last known address, then the requirements of this paragraph (g)(6)(i) are satisfied with respect to the participant and all beneficiaries residing at that address. If a beneficiary's last known address is different from the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(D) *Availability of documentation.* The plan or issuer must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. (For purposes of this paragraph (g), an individual who is not a participant or beneficiary and who presents a notice described in paragraph (g)(6)(i) of this section is considered to be a representative. A representative may request the summary of information by providing the plan a copy of the notice provided to the participant under paragraph (g)(6)(i) of this section with any personally identifiable information redacted.) The summary of information must include the incurred expenditures, the base period, the dollar amount of claims incurred during the base period that would have been denied under the terms of the plan or coverage absent amendments required to comply with paragraphs (b) and (c) of this section, the administrative costs related to those claims, and other administrative costs attributable to complying with the requirements of this section. In no event should the summary of information include any personally identifiable information.

(ii) *Federal agencies*—(A) *Content of notice.* The notice to the Secretary must include the following information:

(*1*) A description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost exemption under this paragraph (g) by such plan (or coverage);

(*2*) For both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits; and

(*3*) For both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(B) *Reporting by health insurance coverage offered in connection with a church plan.* See 26 CFR 54.9812(g)(6)(ii)(B) for delivery with respect to church plans.

(C) *Reporting by health insurance coverage offered in connection with a group health plans subject to Part 7 of Subtitle B of Title I of ERISA.* See 29 CFR 2590.712(g)(6)(ii) for delivery with respect to group health plans subject to ERISA.

(D) *Reporting with respect to non-Federal governmental plans and health insurance issuers in the individual market.* A group health plan that is a non-Federal governmental plan, or a health insurance issuer offering health insurance coverage in the individual market, claiming the exemption of this paragraph (g) for any benefit package must provide notice to the

Department of Health and Human Services. This requirement is satisfied if the plan or issuer sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (g)(6)(ii)(A) of this section identifying the benefit package to which the exemption applies.

(iii) *Confidentiality.* A notification to the Secretary under this paragraph (g)(6) shall be confidential. The Secretary shall make available, upon request and not more than on an annual basis, an anonymous itemization of each notification that includes—

(A) A breakdown of States by the size and type of employers submitting such notification; and

(B) A summary of the data received under paragraph (g)(6)(ii) of this section.

(iv) *Audits.* The Secretary may audit the books and records of a group health plan or a health insurance issuer relating to an exemption, including any actuarial reports, during the 6 year period following notification of such exemption under paragraph (g)(6) of this section. A State agency receiving a notification under paragraph (g)(6) of this section may also conduct such an audit with respect to an exemption covered by such notification.

(h) *Sale of nonparity health insurance coverage.* A health insurance issuer may not sell a policy, certificate, or contract of insurance that fails to comply with paragraph (b) or (c) of this section, except to a plan for a year for which the plan is exempt from the requirements of this section because the plan meets the requirements of paragraph (f) or (g) of this section.

(i) *Applicability dates*—(1) *In general.* Except as provided in paragraph (i)(2) of this section, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014. Until the applicability date, plans and issuers are required to continue to comply with the corresponding sections of § 146.136 contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2013.

(2) *Special effective date for certain collectively-bargained plans.* For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the date on which the last of the collective bargaining agreements terminates (determined without regard to any extension agreed to after October 3, 2008).

SUBPART D—PREEMPTION AND SPECIAL RULES

§ 146.143 Preemption; State flexibility; construction.

(a) *Continued applicability of State law with respect to health insurance issuers.* Subject to paragraph (b) of this section and except as provided in paragraph (c) of this section, part A of title XXVII of the PHS Act is not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

(b) *Continued preemption with respect to group health plans.* Nothing in part A of title XXVII of the PHS Act affects or modifies the provisions of section 514 of ERISA with respect to group health plans.

(c) *Special rules*—(1) *In general.* Subject to paragraph (c)(2) of this section, the provisions of part A of title XXVII of the PHS Act relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 2701 of the PHS Act which differs from the standards or requirements specified in section 2701 of the PHS Act.

(2) *Exceptions.* Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision requires special enrollment periods in addition to those required under section 2702 of the Act.

(d) *Definitions*—(1) *State law.* For purposes of this section the term *State law* includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia is treated as a State law rather than a law of the United States.

(2) *State.* For purposes of this section the term *State* includes a State (as defined in § 144.103), any political subdivisions of a State, or any agency or instrumentality of either.

§ 146.145 Special rules relating to group health plans.

(a) *Group health plan*—(1) *Definition.* A group health plan means an employee welfare benefit plan to the extent that the plan provides medical care (including items and services paid for as medical care) to employees (including both current and former employees) or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

(2) *Determination of number of plans.* [Reserved]

(b) *Excepted benefits*—(1) *In general.* The requirements of subparts B and C of this part do not apply to any group health plan (or any group health insurance coverage) in relation to its provision of the benefits described in paragraph (b)(2), (3), (4), or (5) of this section (or any combination of these benefits).

(2) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances—

(i) Coverage only for accident (including accidental death and dismemberment);

(ii) Disability income coverage;

(iii) Liability insurance, including general liability insurance and automobile liability insurance;

(iv) Coverage issued as a supplement to liability insurance;

(v) Workers' compensation or similar coverage;

(vi) Automobile medical payment insurance;

(vii) Credit-only insurance (for example, mortgage insurance); and

(viii) Coverage for on-site medical clinics.

(ix) Travel insurance, within the meaning of § 144.103 of this subchapter.

(3) *Limited excepted benefits*—(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (b)(3)(ii) of this section. In addition, benefits provided under a health flexible spending arrangement (health FSA) are excepted benefits if they satisfy the requirements of paragraph (b)(3)(v) of this section; benefits provided under an employee assistance program are excepted benefits if they satisfy the requirements of paragraph (b)(3)(vi) of this section; benefits provided under limited wraparound coverage are excepted benefits if they satisfy the requirements of paragraph (b)(3)(vii) of this section; and benefits provided under a health reimbursement arrangement or other account-based group health plan, other than a health FSA, are excepted benefits if they satisfy the requirements of paragraph (b)(3)(viii) of this section.

(ii) *Not an integral part of a group health plan.* For purposes of this paragraph (b)(3), benefits are not an integral part of a group health plan (whether the benefits are provided through the same plan, a separate plan, or as the only plan offered to participants) if either paragraph (b)(3)(ii)(A) or (B) are satisfied.

(A) Participants may decline coverage. For example, a participant may decline coverage if the participant can opt out of the coverage upon request, whether or not there is a participant contribution required for the coverage.

(B) Claims for the benefits are administered under a contract separate from claims administration for any other benefits under the plan.

(iii) *Limited scope*—(A) *Dental benefits.* Limited scope dental benefits are benefits substantially all of which are for treatment of the mouth (including any organ or structure within the mouth).

(B) *Vision benefits.* Limited scope vision benefits are benefits substantially all of which are for treatment of the eye.

(iv) *Long-term care.* Long-term care benefits are benefits that are either—

(A) Subject to State long-term care insurance laws;

(B) For qualified long-term care services, as defined in section 7702B(c)(1) of the Internal Revenue Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Internal Revenue Code; or

(C) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(v) *Health flexible spending arrangements.* Benefits provided under a health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) are excepted for a class of participants only if they satisfy the following two requirements—

(A) Other group health plan coverage, not limited to excepted benefits, is made available for the year to the class of participants by reason of their employment; and

(B) The arrangement is structured so that the maximum benefit payable to any participant in the class for a year cannot exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, cannot exceed $500 plus the amount of the participant's salary reduction election). For this purpose, any amount that an employee can elect to receive as taxable income but elects to apply to the health flexible spending arrangement is considered a salary reduction election (regardless of whether the amount is characterized as salary or as a credit under the arrangement).

(vi) *Employee assistance programs.* Benefits provided under employee assistance programs are excepted if they satisfy all of the requirements of this paragraph (b)(3)(vi).

(A) The program does not provide significant benefits in the nature of medical care. For this purpose, the amount, scope and duration of covered services are taken into account.

(B) The benefits under the employee assistance program are not coordinated with benefits under another group health plan, as follows:

(*1*) Participants in the other group health plan must not be required to use and exhaust benefits under the employee assistance program (making the employee assistance program a gatekeeper) before an individual is eligible for benefits under the other group health plan; and

(*2*) Participant eligibility for benefits under the employee assistance program must not be dependent on participation in another group health plan.

(C) No employee premiums or contributions are required as a condition of participation in the employee assistance program.

(D) There is no cost sharing under the employee assistance program.

(vii) *Limited wraparound coverage*. Limited benefits provided through a group health plan that wrap around eligible individual health insurance (or Basic Health Plan coverage described in section 1331 of the Patient Protection and Affordable Care Act); or that wrap around coverage under a Multi-State Plan described in section 1334 of the Patient Protection and Affordable Care Act, collectively referred to as "limited wraparound coverage," are excepted benefits if all of the following conditions are satisfied. For this purpose, eligible individual health insurance is individual health insurance coverage that is not a grandfathered health plan (as described in section 1251 of the Patient Protection and Affordable Care Act and § 147.140 of this subchapter), not a transitional individual health insurance plan (as described in the March 5, 2014 Insurance Standards Bulletin Series – Extension of Transitional Policy through October 1, 2016), and does not consist solely of excepted benefits (as defined in paragraph (b) of this section).

(A) *Covers additional benefits*. The limited wraparound coverage provides meaningful benefits beyond coverage of cost sharing under either the eligible individual health insurance, Basic Health Program coverage, or Multi-State Plan coverage. The limited wraparound coverage must not provide benefits only under a coordination-of-benefits provision and must not consist of an account-based reimbursement arrangement.

(B) *Limited in amount*. The annual cost of coverage per employee (and any covered dependents, as defined in § 144.103 of this subchapter) under the limited wraparound coverage does not exceed the greater of the amount determined under either paragraph (b)(3)(vii)(B)(*1*) or (*2*) of this section. Making a determination regarding the annual cost of coverage per employee must occur on an aggregate basis relying on sound actuarial principles.

(*1*) The maximum permitted annual salary reduction contribution toward health flexible spending arrangements, indexed in the manner prescribed under section 125(i)(2) of the Internal Revenue Code. For this purpose, the cost of coverage under the limited wraparound includes both employer and employee contributions towards coverage and is determined in the same manner as the applicable premium is calculated under a COBRA continuation provision.

(*2*) Fifteen percent of the cost of coverage under the primary plan. For this purpose, the cost of coverage under the primary plan and under the limited wraparound coverage includes both employer and employee contributions towards the coverage and each is determined in the same manner as the applicable premium is calculated under a COBRA continuation provision.

(C) *Nondiscrimination*. All of the conditions of this paragraph (b)(3)(vii)(C) are satisfied.

(*1*) *No preexisting condition exclusion*. The limited wraparound coverage does not impose any preexisting condition exclusion, consistent with the requirements of section 2704 of the PHS Act and § 147.108 of this subchapter.

(*2*) *No discrimination based on health status*. The limited wraparound coverage does not discriminate against individuals in eligibility, benefits, or premiums based on any health factor of an individual (or any dependent of the individual, as defined in § 144.103 of this subchapter), consistent with the requirements of section 2705 of the PHS Act.

(*3*) *No discrimination in favor of highly compensated individuals*. Neither the limited wraparound coverage, nor any other group health plan coverage

offered by the plan sponsor, fails to comply with section 2716 of the PHS Act or fails to be excludible from income for any individual due to the application of section 105(h) of the Internal Revenue Code (as applicable).

(D) *Plan eligibility requirements*. Individuals eligible for the wraparound coverage are not enrolled in excepted benefit coverage under paragraph (b)(3)(v) of this section (relating to health FSAs). In addition, the conditions set forth in either paragraph (b)(3)(vii)(D)(*1*) or (*2*) of this section are met.

(*1*) *Limited wraparound coverage that wraps around eligible individual insurance for persons who are not full-time employees*. Coverage that wraps around eligible individual health insurance (or that wraps around Basic Health Plan coverage) must satisfy all of the conditions of this paragraph (b)(3)(vii)(D)(1).

(*i*) For each year for which limited wraparound coverage is offered, the employer that is the sponsor of the plan offering limited wraparound coverage, or the employer participating in a plan offering limited wraparound coverage, offers to its full-time employees coverage that is substantially similar to coverage that the employer would need to offer to its full-time employees in order not to be subject to a potential assessable payment under the employer shared responsibility provisions of section 4980H(a) of the Internal Revenue Code, if such provisions were applicable; provides minimum value (as defined in section 36B(c)(2)(C)(ii) of the Internal Revenue Code); and is reasonably expected to be affordable (applying the safe harbor rules for determining affordability set forth in 26 CFR 54.4980H-5(e)(2)). If a plan or issuer providing limited wraparound coverage takes reasonable steps to ensure that employers disclose to the plan or issuer necessary information regarding their coverage offered and affordability information, the plan or issuer is permitted to rely on reasonable representations by employers regarding this information, unless the plan or issuer has specific knowledge to the contrary. In the event that the employer that is the sponsor of the plan offering wraparound coverage, or the employer participating in a plan offering wraparound coverage, has no full-time employees for any plan year limited wraparound coverage is offered, the requirement of this paragraph (b)(3)(vii)(D)(*1*)(*i*) is considered satisfied.

(*ii*) Eligibility for the limited wraparound coverage is limited to employees who are reasonably determined at the time of enrollment to not be full-time employees (and their dependents, as defined in § 144.103 of this subchapter), or who are retirees (and their dependents, as defined in § 144.103 of this subchapter). For this purpose, full-time employees are employees who are reasonably expected to work at least an average of 30 hours per week.

(*iii*) Other group health plan coverage, not limited to excepted benefits, is offered to the individuals eligible for the limited wraparound coverage. Only individuals eligible for the other group health plan coverage are eligible for the limited wraparound coverage.

(*2*) *Limited coverage that wraps around Multi-State Plan coverage*. Coverage that wraps around Multi-State Plan coverage must satisfy all of the conditions of this paragraph (b)(3)(vii)(D)(*2*). For this purpose, the

term "full-time employee" means a "full-time employee" as defined in 26 CFR 54.4980H-1(a)(21) who is not in a limited non-assessment period for certain employees (as defined in 26 CFR 54.4980H-1(a)(26)). Moreover, if a plan or issuer providing limited wraparound coverage takes reasonable steps to ensure that employers disclose to the plan or issuer necessary information regarding their coverage offered and contribution levels for 2013 or 2014 (as applicable), and for any year in which limited wraparound coverage is offered, the plan or issuer is permitted to rely on reasonable representations by employers regarding this information, unless the plan or issuer has specific knowledge to the contrary. Consistent with the reporting and evaluation criteria of paragraph (b)(3)(vii)(E) of this section, the Office of Personnel Management may verify that plans and issuers have reasonable mechanisms in place to ensure that contributing employers meet these standards.

(*i*) The limited wraparound coverage is reviewed and approved by the Office of Personnel Management, consistent with the reporting and evaluation criteria of paragraph (b)(3)(vii)(E) of this section, to provide benefits in conjunction with coverage under a Multi- State Plan authorized under section 1334 of the Patient Protection and Affordable Care Act. The Office of Personnel Management may revoke approval if it determines that continued approval is inconsistent with the reporting and evaluation criteria of paragraph (b)(3)(vii)(E) of this section.

(*ii*) The employer offered coverage in the plan year that began in either 2013 or 2014 that is substantially similar to coverage that the employer would need to have offered to its full-time employees in order to not be subject to an assessable payment under the employer shared responsibility provisions of section 4980H(a) of the Internal Revenue Code, if such provisions had been applicable. In the event that a plan that offered coverage in 2013 or 2014 has no full time employees for any plan year limited wraparound coverage is offered, the requirement of this paragraph (b)(3)(vii)(D)(*2*)(*ii*) is considered satisfied.

(*iii*) In the plan year that began in either 2013 or 2014, the employer offered coverage to a substantial portion of full-time employees that provided minimum value (as defined in section 36B(c)(2)(C)(ii) of the Internal Revenue Code) and was affordable (applying the safe harbor rules for determining affordability set forth in 26 CFR 54.4980H-5(e)(2)). In the event that the plan that offered coverage in 2013 or 2014 has no full-time employees for any plan year limited wraparound coverage is offered, the requirement of this paragraph (b)(3)(vii)(D)(*2*)(*iii*) is considered satisfied.

(*iv*) For the duration of the pilot program, as described in paragraph (b)(3)(vii)(F) of this section, the employer's annual aggregate contributions for both primary and limited wraparound coverage are substantially the same as the employer's total contributions for coverage offered to full-time employees in 2013 or 2014.

(E) *Reporting* – (*1*) *Reporting by group health plans and group health insurance issuers.* A self-insured group health plan, or a health insurance issuer, offering or proposing to offer limited wraparound coverage in connection with Multi-State Plan coverage pursuant to paragraph (b)(3)(vii)(D)(*2*) of this section reports to the Office of Personnel Management

(OPM), in a form and manner specified in guidance, information OPM reasonably requires to determine whether the plan or issuer qualifies to offer such coverage or complies with the applicable requirements of this section.

(*2*) *Reporting by group health plan sponsors*. The plan sponsor of a group health plan offering limited wraparound coverage under paragraph (b)(3)(vii) of this section, must report to the Department of Health and Human Services (HHS), in a form and manner specified in guidance, information HHS reasonably requires.

(F) *Pilot program with sunset*—The provisions of paragraph (b)(3)(vii) of this section apply to limited wraparound coverage that is first offered no earlier than January 1, 2016 and no later than December 31, 2018 and that ends no later than on the later of:

(*1*) The date that is three years after the date limited wraparound coverage is first offered; or

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

(viii) *Health reimbursement arrangements (HRAs) and other account-based group health plans.* Benefits provided under an HRA or other account-based group health plan, other than a health FSA, are excepted if they satisfy all of the requirements of this paragraph (b)(3)(viii). See paragraph (b)(3)(v) of this section for the circumstances in which benefits provided under a health FSA are excepted benefits. For purposes of this paragraph (b)(3)(viii), the term "HRA or other account-based group health plan" has the same meaning as "account-based group health plan" set forth in § 147.126(d)(6)(i) of this subchapter, except that the term does not include health FSAs. For ease of reference, an HRA or other account-based group health plan that satisfies the requirements of this paragraph (b)(3)(viii) is referred to as an excepted benefit HRA.

(A) *Otherwise not an integral part of the plan.* Other group health plan coverage that is not limited to excepted benefits and that is not an HRA or other account-based group health plan must be made available by the same plan sponsor for the plan year to the participant.

(B) *Benefits are limited in amount*— (*1*) *Limit on annual amounts made available.* The amounts newly made available for each plan year under the HRA or other account-based group health plan do not exceed $1,800. In the case of any plan year beginning after December 31, 2020, the dollar amount in the preceding sentence shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment. The cost of living adjustment is the percentage (if any) by which the C–CPI–U for the preceding calendar year exceeds the C–CPI–U for calendar year 2019. The term "C–CPI– U" means the Chained Consumer Price Index for All Urban Consumers as published by the Bureau of Labor Statistics of the Department of Labor. The C–CPI–U for any calendar year is the average of the C–CPI–U as of the close of the 12-month period ending on March 31 of such calendar year. The values of the C–CPI–U used for any calendar year shall be the latest values so published as of the date on which the Bureau publishes the initial value of the C–CPI–U for the month of March for the preceding calendar year. Any such increase that is not a multiple of $50 shall be rounded down to the next lowest multiple of $50. The Department of the Treasury and the Internal Revenue Service will publish the adjusted amount for plan years beginning in any calendar year no later than June 1 of the preceding calendar year.

(*2*) *Carryover amounts.* If the terms of the HRA or other account-based group

health plan allow unused amounts to be made available to participants and dependents in later plan years, such carryover amounts are disregarded for purposes of determining whether benefits are limited in amount.

(*3*) *Multiple HRAs or other account-based group health plans.* If the plan sponsor provides more than one HRA or other account-based group health plan to the participant for the same time period, the amounts made available under all such plans are aggregated to determine whether the benefits are limited in amount, except that HRAs or other account-based group health plans that reimburse only excepted benefits are not included in determining whether the benefits are limited in amount.

(C) *Prohibition on reimbursement of certain health insurance premiums.* The HRA or other account-based group health plan must not reimburse premiums for individual health insurance coverage, group health plan coverage (other than COBRA continuation coverage or other continuation coverage), or Medicare Part A, B, C, or D, except that the HRA or other account-based group health plan may reimburse premiums for such coverage that consists solely of excepted benefits. See also, paragraph (b)(3)(viii)(F) of this section.

(D) *Uniform availability.* The HRA or other account-based group health plan is made available under the same terms to all similarly situated individuals, as defined in § 146.121(d), regardless of any health factor (as described in § 146.121(a)).

(E) *Notice requirement.* For plan years beginning on or after January 11, 2021, the HRA or other account-based group health plan must provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps, or other limits on benefits under the plan, and a description or summary of the benefits. This notice must be provided no later than 90 days after an employee becomes a participant and annually thereafter, in a manner reasonably calculated to ensure actual receipt by participants eligible for the HRA or other account-based group health plan.

(F) *Special rule.* The HRA or other account-based group health plan must not reimburse premiums for short-term, limited-duration insurance (as defined in § 144.103 of this subchapter) if the conditions of this paragraph (b)(3)(viii)(F) are satisfied.

(*1*) The HRA or other account-based group health plan is offered by a small employer (as defined in PHS Act section 2791(e)(4)).

(*2*) The other group health plan coverage offered by the employer pursuant to paragraph (b)(3)(viii)(A) of this section is either fully-insured or partially-insured.

(*3*) The Secretary makes a finding, in consultation with the Secretaries of Labor and the Treasury, that the reimbursement of premiums for short-term, limited-duration insurance by excepted benefit HRAs has caused significant harm to the small group market in the state that is the principal place of business of the small employer.

(*4*) The finding by the Secretary is made after submission of a written recommendation by the applicable state authority of such state, in a form and manner specified by HHS. The written recommendation must include evidence that the reimbursement of premiums for short-term, limited-duration insurance by excepted benefit HRAs established by insured or partially-insured small employers in the state has caused significant harm to the state's small group market, including with respect to premiums.

(5) The restriction shall be imposed or discontinued by publication by the Secretary of a notice in the **Federal Register** and shall apply only prospectively and with a reasonable time for plan sponsors to comply.

(4) *Noncoordinated benefits*—(i) *Excepted benefits that are not coordinated.* Coverage for only a specified disease or illness (for example, cancer-only policies) or hospital indemnity or other fixed indemnity insurance is excepted only if it meets each of the conditions specified in paragraph (b)(4)(ii) of this section. To be hospital indemnity or other fixed indemnity insurance, the insurance must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100/day) regardless of the amount of expenses incurred.

(ii) *Conditions.* Benefits are described in paragraph (b)(4)(i) of this section only if—

(A) The benefits are provided under a separate policy, certificate, or contract of insurance;

(B) There is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and

(C) The benefits are paid with respect to an event without regard to whether benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor.

(iii) *Example.* The rules of this paragraph (b)(4) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage through an insurance policy. The policy provides benefits only for hospital stays at a fixed percentage of hospital expenses up to a maximum of $100 a day.

(ii) *Conclusion.* In this *Example,* even though the benefits under the policy satisfy the conditions in paragraph (b)(4)(ii) of this section, because the policy pays a percentage of expenses incurred rather than a fixed dollar amount, the benefits under the policy are not excepted benefits under this paragraph (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 the primary coverage. The preceding sentence is satisfied if the coverage is designed to fill gaps in cost sharing in the primary coverage, such as coinsurance or deductibles, or the coverage is designed to provide benefits for items and services not covered by the primary coverage and that are not essential health benefits (as defined under section 1302(b) of the Patient Protection and Affordable Care Act) in the State where the coverage is issued, or the coverage is designed to both fill such gaps in cost sharing under, and cover such benefits not covered by, the primary coverage. Similar supplemental coverage does not include coverage that becomes secondary or supplemental only under a coordination-of-benefits provision.

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

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage for both active employees and retirees. The coverage for retirees supplements benefits provided by Medicare, but does not meet the requirements for a supplemental policy under section 1882(g)(1) of the Social Security Act.

(ii) *Conclusion.* In this *Example,* the coverage provided to retirees does not meet the definition of supplemental excepted benefits under this paragraph (b)(5) because the coverage is not Medicare supplemental insurance as defined under section 1882(g)(1) of the Social Security Act, is not a TRICARE supplemental program, and is not supplemental to coverage provided under a group health plan.

(c) *Treatment of partnerships.* For purposes of this part:

(1) *Treatment as a group health plan.* Any plan, fund, or program that would not be (but for this paragraph (c)) an employee welfare benefit plan and that is established or maintained by a partnership, to the extent that the plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, is treated (subject to paragraph (c)(2) of this section) as an employee welfare benefit plan that is a group health plan.

(2) *Employment relationship.* In the case of a group health plan, the term *employer* also includes the partnership in relation to any bona fide partner. In addition, the term *employee* also includes any bona fide partner. Whether or not an individual is a bona fide partner is determined based on all the relevant facts and circumstances, including whether the individual performs services on behalf of the partnership.

(3) *Participants of group health plans.* In the case of a group health plan, the term *participant* also includes any individual described in paragraph (c)(3)(i) or (ii) of this section if the individual is, or may become, eligible to receive a benefit under the plan or the individual's beneficiaries may be eligible to receive any such benefit.

(i) In connection with a group health plan maintained by a partnership, the individual is a partner in relation to the partnership.

(ii) In connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the individual is the self-employed individual.

(d) *Determining the average number of employees.* [Reserved]

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).

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (f) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

(b) *Exceptions.* An issuer may nonrenew or discontinue group health insurance coverage offered in the small or large group market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* The plan sponsor has failed to comply with a material plan provision relating to any employer contribution or group participation rules permitted under § 146.150(e) in the case of the small group market or under applicable State law in the case of the large group market.

(4) *Termination of product.* The issuer is ceasing to offer coverage in the market in accordance with paragraph (c) or (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the group health plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 146.150(c); provided the issuer provides notice in accordance with the requirements of paragraph (c)(1) of this section.

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the small or large group market, that product may be discontinued by the issuer in accordance with applicable State law in the particular market only if—

(1) The issuer provides notice in writing, in a form and manner specified by the Secretary, to each plan sponsor provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 days before the date the coverage will be discontinued;

(2) The issuer offers to each plan sponsor provided that particular product the option, on a guaranteed issue basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in that market; and

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or

beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* An issuer may elect to discontinue offering all health insurance coverage in the small or large group market or both markets in a State in accordance with applicable State law only if—

(1) The issuer provides notice in writing to the applicable State authority and to each plan sponsor (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 days prior to the date the coverage will be discontinued; and

(2) All health insurance policies issued or delivered for issuance in the State in the market (or markets) are discontinued and not renewed.

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with § 144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with § 144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (d)(3)(ii)(B) of this section.

(4) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

(e) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage in a market (or markets) in a State as described in paragraph (d) of this section may not issue coverage in the market (or markets) and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(f) *Exception for uniform modification of coverage.* (1) Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the following—

(i) Large group market; and

(ii) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(2) For purposes of paragraph (f)(1)(ii) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

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

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

(3) For purposes of paragraph (f)(1)(ii) of this section, other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product in the small group market meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer is a member of a controlled group (as described in paragraph (d)(4) of this section), any other health insurance issuer that is a member of such controlled group;

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the rate for any plan within the product within an allowable variation of +/- 2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (f)(3)(iii) and (iv) of this section.

(g) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to "plan sponsor" is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

(h) *Notice of renewal of coverage.* If an issuer in the small group market is renewing grandfathered coverage as described in paragraph (a) of this section, or uniformly modifying grandfathered coverage as described in paragraph (f) of this section, the issuer must provide to each plan sponsor written notice of the renewal at least 60 calendar days before the date the coverage will be renewed in a form and manner specified by the Secretary.

§ 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.

SUBPART F—EXCLUSION OF PLANS AND ENFORCEMENT

§ 146.180 Treatment of non-Federal governmental plans.

(a) Opt-out election for self-funded non-Federal governmental plans—(1) Requirements subject to exemption. The PHS Act requirements described in this paragraph are the following:

(i) Limitations on preexisting condition exclusion periods in accordance with section 2701 of the PHS Act as codified before enactment of the Affordable Care Act.

(ii) Special enrollment periods for individuals and dependents described under section 2704(f) of the PHS Act.

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status under section 2705 of the PHS Act, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements under section 2705(a)(6) and 2705(c) through (f) that prohibit discrimination with respect to genetic information.

(iv) Standards relating to benefits for mothers and newborns under section 2725 of the PHS Act.

(v) Parity in mental health and substance use disorder benefits under section 2726 of the PHS Act.

(vi) Required coverage for reconstructive surgery following mastectomies under section 2727 of the PHS Act.

(vii) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(2) *General rule.* For plan years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not provided through health insurance coverage (that is, it is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(3) *Special rule for certain collectively bargained plans.* In the case of a plan that is maintained pursuant to a collective bargaining agreement that was ratified before March 23, 2010, and whose sponsor made an election to exempt its plan from any of the requirements described in paragraphs (a)(1)(i) through (iii) of this section, the provisions of paragraph (a)(2) of this section

apply for plan years beginning after the expiration of the term of the agreement.

(4) *Examples*—

(i) *Example 1.* A non- Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1 of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(ii) *Example 2.* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to five plan years, October 1, 2009 through September 30, 2014. For the plan year that begins on October 1, 2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(5) *Limitations.* (i) An election under this section cannot circumvent a requirement of the PHS Act to the extent the requirement applied to the plan before the effective date of the election.

(A) *Example 1.* A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

(B) [Reserved]

(ii) If a group health plan is co-sponsored by two or more employers, then only plan enrollees of the non- Federal governmental employer(s) with a valid election under this section are affected by the election.

(6) Stop-loss or excess risk coverage. For purposes of this section—

(i) Subject to paragraph (a)(6)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

(ii) Regardless of whether coverage offered by an issuer is designated as "stop-loss" coverage or "excess risk" coverage, if it is regulated as group health insurance under an applicable State law, then for purposes of this section, a non-Federal governmental plan that purchases the coverage is considered to be fully insured. In that event, a plan may not be exempted under this section from the requirements described in paragraph (a)(1) of this section.

(7) Construction. Nothing in this part should be construed as imposing collective bargaining obligations on any party to the collective bargaining process.

(b) *Form and manner of election*—(1) *Election requirements.* The election must meet the following requirements:

(i) Be made in an electronic format in a form and manner as described by the Secretary in guidance.

(ii) Be made in conformance with all of the plan sponsor's rules, including any public hearing requirements.

(iii) Specify the beginning and ending dates of the period to which the election is to apply. This period can be either of the following periods:

(A) A single specified plan year, as defined in § 144.103 of this subchapter.

(B) The "term of the agreement," as specified in paragraph (b)(2) of this section, in the case of a plan governed by collective bargaining.

(iv) Specify the name of the plan and the name and address of the plan administrator, and include the name and telephone number

of a person CMS may contact regarding the election.

(v) State that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through health insurance coverage.

(vi) Specify each requirement described in paragraph (a)(1) of this section from which the plan sponsor elects to exempt the plan.

(vii) Certify that the person signing the election document, including (if applicable) a third party plan administrator, is legally authorized to do so by the plan sponsor.

(viii) Include, as an attachment, a copy of the notice described in paragraph (f) of this section.

(ix) In the case of a plan sponsor submitting one opt-out election for all group health plans subject to the same collective bargaining agreement, include a list of plans subject to the agreement.

(x) In the case of a plan sponsor submitting opt-out elections for more than one group health plan that is not subject to a collective bargaining agreement, submit a separate election document for each such plan.

(2) "*Term of the agreement" defined.* Except as provided in paragraphs (b)(2)(i) and (ii) of this section, for purposes of this section "term of the agreement" means all group health plan years governed by a single collective bargaining agreement.

(i) In the case of a group health plan for which the last plan year governed by a prior collective bargaining agreement expires during the bargaining process for a new agreement, the term of the prior agreement includes all plan years governed by the agreement plus the period of time that precedes the latest of the following dates, as applicable, with respect to the new agreement:

(A) The date of an agreement between the governmental employer and union officials.

(B) The date of ratification of an agreement between the governmental employer and the union.

(C) The date impasse resolution, arbitration or other closure of the collective bargaining process is finalized when agreement is not reached.

(ii) In the case of a group health plan governed by a collective bargaining agreement for which closure is not reached before the last plan year under the immediately preceding agreement expires, the term of the new agreement includes all plan years governed by the agreement excluding the period that precedes the latest applicable date specified in paragraph (b)(2)(i) of this section.

(3) *Construction*—(i) *Dispute resolution.* Nothing in paragraph (b)(1)(ii) of this section should be construed to mean that CMS arbitrates disputes between plan sponsors, participants, beneficiaries, or their representatives regarding whether an election complies with all of a plan sponsor's rules.

(ii) *Future elections not preempted.* If a plan must comply with one or more requirements described in paragraph (a)(1) of this section for a given plan year or period of plan coverage, nothing in this section should be construed as preventing a plan sponsor from submitting an election in accordance with this section for a subsequent plan year or period of plan coverage.

(c) *Filing a timely election*—(1) *Plan not governed by collective bargaining.* Subject to paragraph (c)(4) of this section, if a plan is not governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the plan year.

(2) *Plan governed by a collective bargaining agreement.* Subject to paragraph (d)(4) of this section, if a plan is governed by a collective bargaining agreement that was ratified before March 23, 2010, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the first plan

year governed by a collective bargaining agreement, or by the 45th day after the latest applicable date specified in paragraph (b)(2)(i) of this section, if the 45th day falls on or after the first day of the plan year.

(3) *Special rule for timely filing.* If the latest filing date specified under paragraphs (c)(1) or (c)(2) of this section falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts filings submitted on the next business day.

(4) *Filing extension based on good cause.* CMS may extend the deadlines specified in paragraphs (c)(1) and (2) of this section for good cause if the plan substantially complies with the requirements of paragraph (e) of this section.

(5) *Failure to file a timely election.* Absent an extension under paragraph (c)(4) of this section, a plan sponsor's failure to file a timely election under paragraph (c)(1) or (2) of this section makes the plan subject to all requirements of this part for the entire plan year to which the election would have applied, or, in the case of a plan governed by a collective bargaining agreement, for any plan years under the agreement for which the election is not timely filed.

(d) Additional information required—

(1) *Written notification.* If an election is timely filed, but CMS determines that the election document (or the notice to plan enrollees) does not meet all of the requirements of this section, CMS may notify the plan sponsor, or other entity that filed the election, that it must submit any additional information that CMS has determined is necessary to meet those requirements. The additional information must be filed with CMS by the later of the following dates:

(i) The last day of the plan year.

(ii) The 45th day after the date of CMS's written notification requesting additional information.

(2) *Timely response.* For submissions via hard copy via U.S. Mail, CMS uses the postmark on the envelope in which the additional information is submitted to determine that the information is timely filed as specified under paragraph (d)(1) of this section. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(3) *Failure to respond timely.* CMS may invalidate an election if the plan sponsor, or other entity that filed the election, fails to timely submit the additional information as specified under paragraph (d)(1) of this section.

(e) *Notice to enrollees*—(1) *Mandatory notification.* (i) A plan that makes the election described in this section must notify each affected enrollee of the election, and explain the consequences of the election. For purposes of paragraph (e) of this section, if the dependent(s) of a participant reside(s) with the participant, a plan need only provide notice to the participant.

(ii) The notice must be in writing and, except as provided in paragraph (e)(2) of this section with regard to initial notices, must be provided to each enrollee at the time of enrollment under the plan, and on an annual basis no later than the last day of each plan year (as defined in § 144.103 of this subchapter) for which there is an election.

(iii) A plan may meet the notification requirements of paragraph (e) of this section by prominently printing the notice in a summary plan description, or equivalent description, that it provides to each enrollee at the time of enrollment, and annually. Also, when a plan provides a notice to an enrollee at the time of enrollment, that notice may serve as the initial annual notice for that enrollee.

(2) *Initial notices.* (i) If a plan is not governed by a collective bargaining agreement, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of that plan year, and notice at the time of enrollment to all individuals who enroll during that plan year.

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first

day of the plan year, or within 30 days after the latest applicable date specified in paragraph (b)(2)(i) of this section if the 30th day falls on or after the first day of the plan year. Also, the plan must provide a notice at the time of enrollment to individuals who—

(A) Enroll on or after the first day of the plan year, when closure of the collective bargaining process is reached before the plan year begins; or

(B) Enroll on or after the latest applicable date specified in paragraph (b)(2)(i) of this section if that date falls on or after the first day of the plan year.

(3) *Notice content.* The notice must include at least the following information:

(i) The specific requirements described in paragraph (a)(1) of this section from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

(ii) A statement that Federal law gives the plan sponsor of a self-funded non- Federal governmental plan the right to exempt the plan in whole, or in part, from the listed requirements, and that the plan sponsor has elected to do so.

(iii) A statement identifying which parts of the plan are subject to the election.

(iv) A statement identifying which of the listed requirements, if any, apply under the terms of the plan, or as required by State law, without regard to an exemption under this section.

(f) *Subsequent elections*—(1) *Election renewal.* A plan sponsor may renew an election under this section through subsequent elections. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

(2) *Form and manner of renewal.* Except for the requirement to forward to CMS a copy of the notice to enrollees under paragraph (b)(1)(viii) of this section, the plan sponsor must comply with the election requirements of paragraph (b)(1) of this section. In lieu of providing a copy of the notice under paragraph (b)(1)(viii) of this section, the plan sponsor may include a statement that the notice has been, or will be, provided to enrollees as specified under paragraph (e) of this section.

(3) *Election renewal includes provisions from which plan not previously exempted.* If an election renewal includes a requirement described in paragraph (a)(1) of this section from which the plan sponsor did not elect to exempt the plan for the preceding plan year, the advance notification requirements of paragraph (e)(2) of this section apply with respect to the additional requirement(s) of paragraph (a) of this section from which the plan sponsor is electing to exempt the plan.

(4) *Special rules regarding renewal of an election under a collective bargaining agreement*—(i) If protracted negotiations with respect to a new agreement result in an extension of the term of the prior agreement (as provided under paragraph (b)(2)(i) of this section) under which an election under this section was in effect, the plan must comply with the enrollee notification requirements of paragraph (e)(1) of this section, and, following closure of the collective bargaining process, must file an election renewal with CMS as provided under paragraph (c)(2) of this section.

(ii) If a single plan applies to more than one bargaining unit, and the plan is governed by collective bargaining agreements of varying lengths, paragraph (c)(2) of this section, with respect to an election renewal, applies to the plan as governed by the agreement that results in the earliest filing date.

(g) *Requirements not subject to exemption*—(1) *Genetic information.* Without regard to an election under this section that exempts a non-Federal governmental plan from any or all of the provisions of §§ 146.111 and 146.121, the exemption election must not be construed to exempt the plan from any provisions of this part that pertain to genetic information.

(2) *Enforcement.* CMS enforces these requirements as provided under paragraph (j) of this section.

(h) *Effect of failure to comply with certification and notification requirements*—(1) *Substantial failure*—(i) *General rule.* Except as provided in paragraph (h)(1)(iii) of this section, a substantial failure to comply with paragraph (e) or (g)(1) of this section results in the invalidation of an election under this section with respect to all plan enrollees for the entire plan year. That is, the plan is subject to all requirements of this part for the entire plan year to which the election otherwise would have applied.

(ii) *Determination of substantial failure.* CMS determines whether a plan has substantially failed to comply with a requirement of paragraph (e) or (g)(1) of this section based on all relevant facts and circumstances, including previous record of compliance, gravity of the violation and whether a plan corrects the failure, as warranted, within 30 days of learning of the violation. However, in general, a plan's failure to provide a notice of the fact and consequences of an election under this section to an individual at the time of enrollment, or on an annual basis before a given plan year expires, constitutes a substantial failure.

(iii) *Exceptions*—(A) *Multiple employers.* If the plan is sponsored by multiple employers, and only certain employers substantially fail to comply with the requirements of paragraph (e) or (g)(1) of this section, then the election is invalidated with respect to those employers only, and not with respect to other employers that complied with those requirements, unless the plan chooses to cancel its election entirely.

(B) *Limited failure to provide notice.* If a substantial failure to notify enrollees of the fact and consequences of an election is limited to certain individuals, the election under this section is valid only if, for the plan year with respect to which the failure has occurred, the plan agrees not to apply the election with respect to the individuals who were not notified and so informs those individuals in writing.

(2) *Examples*—

(i) *Example 1.* A self-funded, non-Federal group health plan is co-sponsored by 10 school districts. Nine of the school districts have fully complied with the requirements of paragraph (e) of this section, including providing notice to new employees at the time of their enrollment in the plan, regarding the group health plan's exemption under this section from requirements of this part. One school district, which hired 10 new teachers during the summer for the upcoming school year, neglected to notify three of the new hires about the group health plan's exemption election at the time they enrolled in the plan. The school district has substantially failed to comply with a requirement of paragraph (e) of this section with respect to these individuals. The school district learned of the oversight six weeks into the school year, and promptly (within 30 days of learning of the oversight) provided notice to the three teachers regarding the plan's exemption under this section and that the exemption does not apply to them, or their dependents, during the plan year of their enrollment because of the plan's failure to timely notify them of its exemption. The plan complies with the requirements of this part for these individuals for the plan year of their enrollment. CMS would not require the plan to come into compliance with the requirements of this part for other enrollees.

(ii) *Example 2.* Two non-Federal governmental employers cosponsor a self-funded group health plan. One employer substantially fails to comply with the requirements of paragraph (e) of this section. While the plan may limit the invalidation of the election to enrollees of the plan sponsor that is responsible for the substantial failure, the plan sponsors determine that administering the plan in that manner would be too burdensome. Accordingly, in this example, the plan sponsors choose to cancel the election entirely. Both plan sponsors come into compliance with the requirements of this part with respect to all enrollees for the plan year for which the substantial failure has occurred.

(i) *Election invalidated.* If CMS finds cause to invalidate an election under this section, the following rules apply:

(1) CMS notifies the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) in writing that CMS has made a preliminary determination that an election is invalid, and States the basis for that determination.

(2) CMS's notice informs the plan sponsor that it has 45 days after the date of CMS's notice to explain in writing why it believes its election is valid. The plan sponsor should provide applicable

statutory and regulatory citations to support its position.

(3) CMS verifies that the plan sponsor's response is timely filed as provided under paragraph (c)(3) of this section. CMS will not consider a response that is not timely filed.

(4) If CMS's preliminary determination that an election is invalid remains unchanged after CMS considers the plan sponsor's timely response (or in the event that the plan sponsor fails to respond timely), CMS provides written notice to the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) of CMS's final determination that the election is invalid. Also, CMS informs the plan sponsor that, within 45 days of the date of the notice of final determination, the plan, subject to paragraph (i)(1)(iii) of this section, must comply with all requirements of this part for the specified period for which CMS has determined the election to be invalid.

(j) *Enforcement.* To the extent that an election under this section has not been filed or a non-Federal governmental plan otherwise is subject to one or more requirements of this part, CMS enforces those requirements under part 150 of this subchapter. This may include imposing a civil money penalty against the plan or plan sponsor, as determined under subpart C of part 150.

(k) *Construction.* Nothing in this section should be construed to prevent a State from taking the following actions:

(1) Establishing, and enforcing compliance with, the requirements of State law (as defined in § 146.143(d)(1)), including requirements that parallel provisions of title XXVII of the PHS Act, that apply to non-Federal governmental plans or sponsors.

(2) Prohibiting a sponsor of a non-Federal governmental plan within the State from making an election under this section.

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

Authority: 42 U.S.C. 300gg through 300gg– 63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

§ 147.100 Basis and scope.

Part 147 of this subchapter implements the requirements of the Patient Protection and Affordable Care Act that apply to group health plans and health insurance issuers in the Group and Individual markets.

§ 147.102 Fair health insurance premiums.

(a) *In general.* With respect to the premium rate charged by a health insurance issuer in accordance with § 156.80 of this subchapter for health insurance coverage offered in the individual or small group market—

(1) The rate may vary with respect to the particular plan or coverage involved only by determining the following:

(i) Whether the plan or coverage covers an individual or family.

(ii) Rating area, as established in accordance with paragraph (b) of this section. For purposes of this paragraph (a), rating area is determined—

(A) In the individual market, using the primary policyholder's address.

(B) In the small group market, using the group policyholder's principal business address. For purposes of this paragraph (a)(1)(ii)(B), principal business address means the principal business address registered with the State or, if a principal business address is not registered with the State, or is registered solely for purposes of service of process and is not a substantial worksite for the policyholder's business, the business address within the State where the greatest number of employees of such policyholder works. If, for a network plan, the group policyholder's principal business address is not within the service area of such plan, and the policyholder has employees who live, reside, or work within the service area, the principal business address for purposes of the network plan is the business address within the plan's service area where the greatest number of employees work as of the beginning of the plan year. If there is no such business address, the rating area for purposes of the network plan is the rating area that reflects where the greatest number of employees within the plan's service area live or reside as of the beginning of the plan year.

(iii) Age, except that the rate may not vary by more than 3:1 for like individuals of different age who are age 21 and older and that the variation in rate must be actuarially justified for individuals under age 21, consistent with the uniform age rating curve under paragraph (e) of this section. For purposes of identifying the appropriate age adjustment under this paragraph and the age band under paragraph (d) of this section applicable to a specific enrollee, the enrollee's age as of the date of policy issuance or renewal must be used.

(iv) Subject to section 2705 of the Public Health Service Act and its implementing regulations (related to prohibiting discrimination based on health status and programs of health promotion or disease prevention) as applicable, tobacco use, except that such rate may not vary by more than 1.5:1 and may only be applied with respect to individuals who may legally use tobacco under federal and state law. For purposes of this section, tobacco use means use of tobacco on average four or more times per week within no longer than the past 6 months. This includes all tobacco products, except that tobacco use does not include religious or ceremonial use of tobacco. Further, tobacco use must be defined in terms of when a tobacco product was last used.

(2) The rate must not vary with respect to the particular plan or coverage involved by any other

factor not described in paragraph (a)(1) of this section.

(b) *Rating area.* (1) A state may establish one or more rating areas within that state, as provided in paragraphs (b)(3) and (b)(4) of this section, for purposes of applying this section and the requirements of title XXVII the Public Health Service Act and title I of the Patient Protection and Affordable Care Act.

(2) If a state does not establish rating areas as provided in paragraphs (b)(3) and (b)(4) of this section or provide information on such rating areas in accordance with § 147.103, or CMS determines in accordance with paragraph (b)(5) of this section that a state's rating areas under paragraph (b)(4) of this section are not adequate, the default will be one rating area for each metropolitan statistical area in the state and one rating area comprising all non-metropolitan statistical areas in the state, as defined by the Office of Management and Budget.

(3) A state's rating areas must be based on the following geographic boundaries: Counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas, as defined by the Office of Management and Budget, and will be presumed adequate if either of the following conditions are satisfied:

(i) The state established by law, rule, regulation, bulletin, or other executive action uniform rating areas for the entire state as of January 1, 2013.

(ii) The state establishes by law, rule, regulation, bulletin, or other executive action after January 1, 2013 uniform rating areas for the entire state that are no greater in number than the number of metropolitan statistical areas in the state plus one.

(4) Notwithstanding paragraph (b)(3) of this section, a state may propose to CMS for approval a number of rating areas that is greater than the number described in paragraph (b)(3)(ii) of this section, provided such rating areas are based on the geographic boundaries specified in paragraph (b)(3) of this section.

(5) In determining whether the rating areas established by each state under paragraph (b)(4) of this section are adequate, CMS will consider whether the state's rating areas are actuarially justified, are not unfairly discriminatory, reflect significant differences in health care unit costs, lead to stability in rates over time, apply uniformly to all issuers in a market, and are based on the geographic boundaries of counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas.

(c) *Application of variations based on age or tobacco use.* With respect to family coverage under health insurance coverage, the rating variations permitted under paragraphs (a)(1)(iii) and (a)(1)(iv) of this section must be applied based on the portion of the premium attributable to each family member covered under the coverage.

(1) *Per-member rating.* The total premium for family coverage must be determined by summing the premiums for each individual family member. With respect to family members under the age of 21, the premiums for no more than the three oldest covered children must be taken into account in determining the total family premium.

(2) *Family tiers under community rating.* If a state does not permit any rating variation for the factors described in paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the state may require that premiums for family coverage be determined by using uniform family tiers and the corresponding multipliers established by the state. If a state does not establish uniform family tiers and the corresponding multipliers, the per-member-rating methodology under paragraph (c)(1) of this section will apply in that state.

(3) *Application to small group market*—(i) In the case of the small group market, the total premium charged to a group health plan is determined by summing the premiums of covered participants and beneficiaries in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(ii) Subject to paragraph (c)(3)(iii) of this section, nothing in this section prevents a state from requiring issuers to offer to a group health plan, or an issuer from voluntarily offering to a group health plan, premiums that are based on average enrollee premium

amounts, provided that the total group premium established at the time of applicable enrollment at the beginning of the plan year is the same total amount derived in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(iii) Effective for plan years beginning on or after January 1, 2015, an issuer that, in connection with a group health plan in the small group market, offers premiums that are based on average enrollee premium amounts under paragraph (c)(3)(ii) of this section must—

(A) Ensure an average enrollee premium amount calculated based on applicable enrollment of participants and beneficiaries at the beginning of the plan year does not vary during the plan year.

(B) Unless a state establishes and CMS approves an alternate rating methodology, calculate an average enrollee premium amount for covered individuals age 21 and older, and calculate an average enrollee premium amount for covered individuals under age 21. The premium for a given family composition is determined by summing the average enrollee premium amount applicable to each family member covered under the plan, taking into account no more than three covered children under age 21.

(C) Pursuant to applicable state law, ensure that the average enrollee premium amount calculated for any individual covered under the plan does not include any rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section. The rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section is determined based on the premium rate that would be applied on a per-member basis with respect to an individual who uses tobacco and then included in the premium charged for that individual.

(D) To the extent permitted by applicable State law and, in the case of coverage offered through a SHOP, as permitted by the SHOP, apply this paragraph (c)(3)(iii) uniformly among group health plans enrolling in that product, giving those group health plans the option to pay premiums based on average enrollee premium amounts.

(d) *Uniform age bands.* The following uniform age bands apply for rating purposes under paragraph (a)(1)(iii) of this section:

(1) *Child age bands.* (i) For plan years or policy years beginning before January 1, 2018, a single age band for individuals age 0 through 20.

(ii) For plan years or policy years beginning on or after January 1, 2018:

(A) A single age band for individuals age 0 through 14.

(B) One-year age bands for individuals age 15 through 20.

(2) *Adult age bands.* One-year age bands for individuals age 21 through 63.

(3) *Older adult age bands.* A single age band for individuals age 64 and older.

(e) *Uniform age rating curves.* Each State may establish a uniform age rating curve in the individual or small group market, or both markets, for rating purposes under paragraph (a)(1)(iii) of this section. If a State does not establish a uniform age rating curve or provide information on such age curve in accordance with § 147.103, a default uniform age rating curve specified in guidance by the Secretary to reflect market patterns in the individual and small group markets will apply in that State that takes into account the rating variation permitted for age under State law.

(f) *Special rule for large group market.* If a state permits health insurance issuers that offer coverage in the large group market in the state to offer such coverage through an Exchange starting in 2017, the provisions of this section applicable to coverage in the small group market apply to all coverage offered in the large group market in the state.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

§ 147.103 State reporting.

(a) *2014.* If a state has adopted or intends to adopt for the 2014 plan or policy year a standard or requirement described in this paragraph, the state must submit to CMS information about such standard or requirement in a form and manner specified in guidance by the Secretary no later than March 29, 2013. A state standard or requirement is described in this paragraph if it includes any of the following:

(1) A ratio narrower than 3:1 in connection with establishing rates for individuals who are age 21 and older, pursuant to § 147.102(a)(1)(iii).

(2) A ratio narrower than 1.5:1 in connection with establishing rates for individuals who use tobacco legally, pursuant to § 147.102(a)(1)(iv).

(3) Geographic rating areas, pursuant to § 147.102(b).

(4) In states that do not permit rating based on age or tobacco use, uniform family tiers and corresponding multipliers, pursuant to § 147.102(c)(2).

(5) A requirement that that issuers in the small group market offer to a group premiums that are based on average enrollee amounts, pursuant to paragraph § 147.102(c)(3).

(6) A uniform age rating curve, pursuant to § 147.102(e).

(b) *Updates.* If a state adopts a standard or requirement described in paragraph (a) of this section for any plan or policy year beginning after the 2014 plan or policy year (or updates a standard or requirement that applies for the 2014 plan or policy year), the state must submit to CMS information about such standard in a form and manner specified in guidance by the Secretary.

(c) *Applicability date.* The provisions of this section apply on March 29, 2013.

§ 147.104 Guaranteed availability of coverage.

(a) *Guaranteed availability of coverage in the individual and group market.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer that offers health insurance coverage in the individual, small group, or large group market in a State must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.

(b) *Enrollment periods.* A health insurance issuer may restrict enrollment in health insurance coverage to open or special enrollment periods.

(1) *Open enrollment periods*—(i) *Group market.* (A) Subject to paragraph (b)(1)(i)(B) of this section, a health insurance issuer in the group market must allow an employer to purchase health insurance coverage for a group health plan at any point during the year.

(B) In the case of a group health plan in the small group market that cannot comply with employer contribution or group participation rules for the offering of health insurance coverage, as allowed under applicable State law, and in the case of a QHP offered in the SHOP, as permitted by § 156.285(e) or § 156.286(e) of this subchapter, a health insurance issuer may restrict the availability of coverage to an annual enrollment period that begins November 15 and extends through December 15 of each calendar year.

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a SHOP in a State, for a group enrollment received on the first through the fifteenth day of any month, the coverage effective date must be no later than the first day of the following month. For a group enrollment received on the 16th through last day of any month, the coverage effective date must be no later than the first day of the second following month. In

either such case, a small employer may instead opt for a later effective date within a quarter for which small group market rates are available.

(ii) *Individual market.* A health insurance issuer in the individual market must allow an individual to purchase health insurance coverage during the initial and annual open enrollment periods described in § 155.410(b) and (e) of this subchapter. Coverage must become effective consistent with the dates described in § 155.410(c) and (f) of this subchapter.

(2) *Limited open enrollment periods.* (i) A health insurance issuer in the individual market must provide a limited open enrollment period for the triggering events described in § 155.420(d) of this subchapter, excluding, with respect to coverage offered outside of an Exchange, the following:

(A) Section 155.420(d)(3) of this subchapter (concerning Exchange eligibility standards);

(B) Section 155.420(d)(6) of this subchapter (to the extent concerning eligibility for advance payments of the premium tax credit or change in eligibility for cost-sharing reductions other than ineligibility);

(C) Section 155.420(d)(8) of this subchapter (concerning Indians);

(D) Section 155.420(d)(9) of this subchapter (concerning exceptional circumstances);

(E) Section 155.420(d)(12) of this subchapter (concerning plan and benefit display errors);

(F) Section 155.420(d)(13) of this subchapter (concerning eligibility for insurance affordability programs or enrollment in the Exchange); and

(G) Section 155.420(d)(16) of this subchapter (concerning eligibility for advance payments of the premium tax credit and household income, as defined in 26 CFR 1.36B–1(e), that is expected to be no greater than 150 percent of the Federal poverty level).

(ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in §§ 155.420(a)(5) and (d)(4)) of this subchapter to a "QHP" is deemed to refer to a plan, a reference to "the Exchange" is deemed to refer to the applicable State authority, and a reference to a "qualified individual" is deemed to refer to an individual in the individual market. For purposes of § 155.420(d)(4) of this subchapter, "the Exchange" is deemed to refer to the Exchange or the health plan, as applicable.

(iii) Notwithstanding anything to the contrary in § 155.420(d) of this subchapter, § 155.420(a)(4) of this subchapter does not apply to limited open enrollment periods under paragraph (b)(2) of this section.

(3) *Special enrollment periods.* A health insurance issuer in the group and individual market must establish special enrollment periods for qualifying events as defined under section 603 of the Employee Retirement Income Security Act of 1974, as amended. These special enrollment periods are in addition to any other special enrollment periods that are required under federal and state law.

(4) *Length of enrollment periods.* (i) In the group market, enrollees must be provided 30 calendar days after the date of the qualifying event described in paragraph (b)(3) of this section to elect coverage.

(ii) In the individual market, subject to § 155.420(c)(5) of this subchapter, individuals must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in § 155.420(c)(2) of this subchapter.

(5) *Effective date of coverage for limited open and special enrollment periods.* With respect to an election made under paragraph (b)(2) or (b)(3) of this section, coverage must become effective

consistent with the dates described in § 155.420(b) of this subchapter.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the group and individual market through a network plan, the issuer may do the following:

(i) Limit the employers that may apply for the coverage to those with eligible individuals in the group market who live, work, or reside in the service area for the network plan, and limit the individuals who may apply for the coverage in the individual market to those who live or reside in the service area for the network plan.

(ii) Within the service area of the plan, deny coverage to employers and individuals if the issuer has demonstrated to the applicable state authority (if required by the state authority) the following:

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups or any additional individuals because of its obligations to existing group contract holders and enrollees.

(B) It is applying paragraph (c)(1) of this section uniformly to all employers and individuals without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status- related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to an individual or an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the individual, small group, or large group market, as applicable, for a period of 180 calendar days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the group or individual market if the issuer has demonstrated to the applicable state authority (if required by the state authority) the following:

(i) It does not have the financial reserves necessary to offer additional coverage.

(ii) It is applying this paragraph (d)(1) uniformly to all employers or individual in the large group, small group, or individual market, as applicable, in the State consistent with applicable State law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to any employer or individual in a state under paragraph (d)(1) of this section may not offer coverage in the large group, small group, or individual market, as applicable, in the State before the later of either of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable state authority, if required under applicable state law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable state authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions.

(f) *Calendar year plans.* An issuer that offers coverage in the individual market, or in a merged market in a State that has elected to merge the individual market and small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, must ensure that such coverage is offered on a calendar year basis with a policy year ending on December 31 of each calendar year.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

(i) *Coverage denials for failure to pay premiums for prior coverage.* A health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates paragraph (a) of this section.

(j) *Construction.* Nothing in this section should be construed to require an issuer to offer coverage otherwise prohibited under applicable Federal law.

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (e) of this section, a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

(b) *Exceptions.* An issuer may nonrenew or discontinue health insurance coverage offered in the group or individual market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor or individual, as applicable, has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor or individual, as applicable, has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* In the case of group health insurance coverage, the plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, pursuant to applicable state law. For purposes of this paragraph the following apply:

(i) The term "employer contribution rule" means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries.

(ii) The term "group participation rule" means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(4) *Termination of product.* The issuer is ceasing to offer coverage in the market in accordance with paragraph (c) or (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 147.104(c)(1)(i); provided the issuer provides notice in accordance

with the requirements of paragraph (c)(1) of this section.

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the bona fide association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the group or individual market, that product may be discontinued by the issuer in accordance with applicable state law in the applicable market only if the following occurs:

(1) The issuer provides notice in writing, in a form and manner specified by the Secretary, to each plan sponsor or individual, as applicable, provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 calendar days before the date the coverage will be discontinued.

(2) The issuer offers to each plan sponsor or individual, as applicable, provided that particular product the option, on a guaranteed availability basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan or individual health insurance coverage in that market.

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or individuals, as applicable, or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* (1) An issuer may elect to discontinue offering all health insurance coverage in the individual, small group, or large group market, or all markets, in a State in accordance with applicable State law only if—

(i) The issuer provides notice in writing to the applicable state authority and to each plan sponsor or individual, as applicable, (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 calendar days prior to the date the coverage will be discontinued; and

(ii) All health insurance policies issued or delivered for issuance in the state in the applicable market (or markets) are discontinued and not renewed.

(2) An issuer that elects to discontinue offering all health insurance coverage in a market (or markets) in a state as described in this paragraph (d) may not issue coverage in the applicable market (or markets) and state involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with § 144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with § 144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (d)(3)(ii)(B) of this section.

(4) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

(e) *Exception for uniform modification of coverage.* (1) Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan or an individual, as applicable, in the following:

(i) Large group market.

(ii) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(iii) Individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

(2) For purposes of paragraphs (e)(1)(ii) and (iii) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

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

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

(3) Other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product in the individual or small group market meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer is a member of a controlled group (as described in paragraph (d)(4) of this section), any other health insurance issuer that is a member of such controlled group);

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the plan-adjusted index rate (as described in § 156.80(d)(2) of this subchapter) for any plan within the product within an allowable variation of +/-2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (e)(3)(iii) and (iv) of this section.

(f) *Notice of renewal of coverage.* (1) If an issuer in the individual market is renewing non-grandfathered coverage as described in paragraph (a) of this section, or uniformly modifying non-grandfathered coverage

as described in paragraph (e) of this section, the issuer must provide to each individual written notice of the renewal before the date of the first day of the next annual open enrollment period in a form and manner specified by the Secretary.

(2) If an issuer in the small group market is renewing coverage as described in paragraph (a) of this section, or uniformly modifying coverage as described in paragraph (e) of this section, the issuer must provide to each plan sponsor written notice of the renewal at least 60 calendar days before the date of the coverage will be renewed in a form and manner specified by the Secretary.

(g) *Notification of change of ownership.* If an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan experiences a change of ownership, as recognized by the State in which the plan is offered, the issuer must notify HHS in a manner specified by HHS, by the latest of—

(1) The date the transaction is entered into; or

(2) The 30th day prior to the effective date of the transaction.

(h) *Construction.* (1) Nothing in this section should be construed to require an issuer to renew or continue in force coverage for which continued eligibility would otherwise be prohibited under applicable Federal law.

(2) Medicare entitlement or enrollment is not a basis to nonrenew an individual's health insurance coverage in the individual market under the same policy or contract of insurance.

(i) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to "plan sponsor" is deemed, with respect to coverage provided to an employer member of the association, to include a reference to the employer.

(j) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(k) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

§ 147.108 Prohibition of preexisting condition exclusions.

(a) *In general.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103 of this subchapter).

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

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P.* At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N. N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1,* the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. Therefore, such an exclusion is prohibited.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M. M* denies *C*'s application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion. See Example 2* in § 146.111(a)(2) of this subchapter for a conclusion that *M*'s denial of *C*'s application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(c) *Allowable screenings to determine eligibility for alternative coverage in the individual market*—(1) *In general.* (i) A health insurance issuer offering individual health insurance coverage may screen applicants for eligibility for alternative coverage options before offering a child-only policy if—

(A) The practice is permitted under State law;

(B) The screening applies to all child-only applicants, regardless of health status; and

(C) The alternative coverage options include options for which healthy children would potentially be eligible (*e.g.*, Children's Health Insurance Program (CHIP) or group health insurance).

(ii) An issuer must provide such coverage to an applicant effective on the first date that a child-only policy would have been effective had the applicant not been screened for an alternative coverage option, as provided by State law. A State may impose a reasonable time limit by when an issuer would have to enroll a child regardless of pending applications for other coverage.

(2) *Restrictions.* A health insurance issuer offering individual health insurance coverage may screen applicants for eligibility for alternative coverage provided that:

(i) The screening process does not by its operation significantly delay enrollment or artificially engineer eligibility of a child for a program targeted to individuals with a pre-existing condition;

(ii) The screening process is not applied to offers of dependent coverage for children; or

(ii) (*sic—should be* (iii)) The issuer does not consider whether an applicant is eligible for, or is provided medical assistance under, Medicaid in making enrollment decisions, as provided under 42 U.S.C. 1396a (25)(G).

(d) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

§ 147.110 Prohibiting discrimination against participants, beneficiaries, and individuals based on a health factor.

(a) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must comply with all the requirements under 45 CFR 146.121 applicable to a group health plan and a health insurance issuer offering group health insurance coverage. Accordingly, with respect to an issuer offering health insurance coverage in the individual market, the issuer is subject to the requirements of § 146.121 to the same extent as an issuer offering group health insurance coverage, except the exception contained in § 146.121(f) (concerning nondiscriminatory wellness programs) does not apply.

(b) *Applicability date.* This section is applicable to group health plans and health insurance issuers offering group or individual health insurance coverage for plan years (in the individual market, policy years) beginning on or after January 1, 2014. See § 147.140, which provides that the rules of this section do not apply to grandfathered health plans that are individual health insurance coverage.

§ 147.116 Prohibition on waiting periods that exceed 90 days.

(a) *General rule.* A group health plan, and a health insurance issuer offering group health insurance coverage, must not apply any waiting period that exceeds 90 days, in accordance with the rules of this section. If, under the terms of a plan, an individual can elect coverage that would begin on a date that is not later than the end of the 90-day waiting period, this paragraph (a) is considered satisfied. Accordingly, in that case, a plan or issuer will not be considered to have violated this paragraph (a) solely because individuals take, or are permitted to take, additional time (beyond the end of the 90-day waiting period) to elect coverage.

(b) *Waiting period defined.* For purposes of this part, a waiting period is the period that must pass before coverage for an individual who is otherwise eligible to enroll under the terms of a group health plan can become effective. If an individual enrolls as a late enrollee (as defined under § 144.103 of this subchapter) or special enrollee (as described in § 146.117 of this subchapter), any period before such late or special enrollment is not a waiting period.

(c) *Relation to a plan's eligibility criteria*—(1) *In general.* Except as provided in paragraphs (c)(2) and (c)(3) of this section, being otherwise eligible to enroll under the terms of a group health plan means having met the plan's substantive eligibility conditions (such as, for example, being in an eligible job classification, achieving job-related licensure requirements specified in the plan's terms, or satisfying a reasonable and bona fide employment-based orientation period). Moreover, except as provided in paragraphs (c)(2) and (c)(3) of this section, nothing in this section requires a plan sponsor to offer coverage to any particular individual or class of individuals (including, for example, part-time employees). Instead, this section prohibits requiring otherwise eligible individuals to wait more than 90 days before coverage is effective. *See also* section 4980H of the Code and its implementing regulations for an applicable large employer's shared responsibility to provide health coverage to full-time employees.

(2) *Eligibility conditions based solely on the lapse of time.* Eligibility conditions that are based solely on the lapse of a time period are permissible for no more than 90 days.

(3) *Other conditions for eligibility.* Other conditions for eligibility under the terms of a group health plan are generally permissible under PHS Act section 2708, unless the condition is designed to avoid compliance with the 90-day waiting period limitation, determined in accordance with the rules of this paragraph (c)(3).

(i) *Application to variable-hour employees in cases in which a specified number of hours of service per period is a plan eligibility condition.* If a group health plan conditions eligibility on an employee regularly having a specified number of hours of service per period (or working full-time), and it cannot be determined that a newly-hired employee is reasonably expected to regularly work that number of hours per period (or work full-time), the plan may take a reasonable period of time, not to exceed 12 months and beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date, to determine whether the employee meets the plan's eligibility condition. Except in cases in which a waiting period that exceeds 90 days is imposed in addition to a measurement period, the time period for determining whether such an employee meets the plan's eligibility condition will not be considered to be designed to avoid compliance with the 90-day waiting period limitation if coverage is made effective no later than 13 months from the employee's start date plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month.

(ii) *Cumulative service requirements.* If a group health plan or health insurance issuer conditions eligibility on an employee's having completed a number of cumulative hours of service, the eligibility condition is not considered to be designed to avoid compliance with the 90-day waiting period limitation if the cumulative hours-of-service requirement does not exceed 1,200 hours.

(iii) *Limitation on orientation periods.* To ensure that an orientation period is not used as a subterfuge for the passage of time, or designed to avoid compliance with the 90-day waiting period limitation, an orientation period is permitted only if it does not exceed one month. For this purpose, one month is determined by adding one calendar month and subtracting one calendar day, measured from an employee's start date in a position that is otherwise eligible for coverage. For example, if an employee's start date in an otherwise eligible position is May 3, the last permitted day of the orientation period is June 2. Similarly, if an employee's start date in an otherwise eligible position is October 1, the last permitted day of the orientation period is October 31. If there is not a corresponding date in the next calendar month upon adding a calendar month, the last permitted day of the orientation period is the last day of the next calendar month. For example, if the employee's start date is January 30, the last permitted day of the orientation period is February 28 (or February 29 in a leap year). Similarly, if the employee's start date is August 31, the last permitted day of the orientation period is September 30.

(d) *Application to rehires.* A plan or issuer may treat an employee whose employment has terminated and

who then is rehired as newly eligible upon rehire and, therefore, required to meet the plan's eligibility criteria and waiting period anew, if reasonable under the circumstances (for example, the termination and rehire cannot be a subterfuge to avoid compliance with the 90-day waiting period limitation).

(e) *Counting days.* Under this section, all calendar days are counted beginning on the enrollment date (as defined in § 144.103), including weekends and holidays. A plan or issuer that imposes a 90-day waiting period may, for administrative convenience, choose to permit coverage to become effective earlier than the 91st day if the 91st day is a weekend or holiday.

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

Example 1. (i) *Facts.* A group health plan provides that full-time employees are eligible for coverage under the plan. Employee *A* begins employment as a full-time employee on January 19.

(ii) *Conclusion.* In this *Example 1*, any waiting period for *A* would begin on January 19 and may not exceed 90 days. Coverage under the plan must become effective no later than April 19 (assuming February lasts 28 days).

Example 2. (i) *Facts.* A group health plan provides that only employees with job title *M* are eligible for coverage under the plan. Employee *B* begins employment with job title *L* on January 30.

(ii) *Conclusion.* In this *Example 2*, *B* is not eligible for coverage under the plan, and the period while *B* is working with job title *L* and therefore not in an eligible class of employees, is not part of a waiting period under this section.

Example 3. (i) *Facts.* Same facts as in *Example 2*, except that *B* transfers to a new position with job title *M* on April 11.

(ii) *Conclusion.* In this *Example 3*, *B* becomes eligible for coverage on April 11, but for the waiting period. Any waiting period for *B* begins on April 11 and may not exceed 90 days; therefore, coverage under the plan must become effective no later than July 10.

Example 4. (i) *Facts.* A group health plan provides that only employees who have completed specified training and achieved specified certifications are eligible for coverage under the plan. Employee *C* is hired on May 3 and meets the plan's eligibility criteria on September 22.

(ii) *Conclusion.* In this *Example 4*, *C* becomes eligible for coverage on September 22, but for the waiting period. Any waiting period for *C* would begin on September 22 and may not exceed 90 days; therefore, coverage under the plan must become effective no later than December 21.

Example 5. (i) *Facts.* A group health plan provides that employees are eligible for coverage after one year of service.

(ii) *Conclusion.* In this *Example 5*, the plan's eligibility condition is based solely on the lapse of time and, therefore, is impermissible under paragraph (c)(2) of this section because it exceeds 90 days.

Example 6. (i) *Facts.* Employer *V*'s group health plan provides for coverage to begin on the first day of the first payroll period on or after the date an employee is hired and completes the applicable enrollment forms. Enrollment forms are distributed on an employee's start date and may be completed within 90 days. Employee *D* is hired and starts on October 31, which is the first day of a pay period. *D* completes the enrollment forms and submits them on the 90th day after *D*'s start date, which is January 28. Coverage is made effective 7 days later, February 4, which is the first day of the next pay period.

(ii) *Conclusion.* In this *Example 6*, under the terms of *V*'s plan, coverage may become effective as early as October 31, depending on when *D* completes the applicable enrollment forms. Under the terms of the plan, when coverage becomes effective depends solely on the length of time taken by *D* to complete the enrollment materials. Therefore, under the terms of the plan, *D* may elect coverage that would begin on a date that does not exceed the 90-day waiting period limitation, and the plan complies with this section.

Example 7. (i) *Facts.* Under Employer *W*'s group health plan, only employees who are full-time (defined under the plan as regularly averaging 30 hours of service per week) are eligible for coverage. Employee *E* begins employment for Employer *W* on November 26 of Year 1. *E*'s hours are reasonably expected to vary, with an opportunity to work between 20 and 45 hours per week, depending on shift availability and *E*'s availability. Therefore, it cannot be determined at *E*'s start date that *E* is reasonably expected to work full-time. Under the terms of the plan, variable-hour employees, such as *E*, are eligible to enroll in the plan if they are determined to be a full-time employee after a measurement period of 12 months that begins on the employee's start date. Coverage is made effective no later than the first day of the first calendar month after the applicable enrollment forms are received. *E*'s 12-month measurement period ends November 25 of Year 2. *E* is determined to be a full-time employee and is

notified of *E*'s plan eligibility. If *E* then elects coverage, *E*'s first day of coverage will be January 1 of Year 3.

(ii) *Conclusion.* In this *Example 7*, the measurement period is permissible because it is not considered to be designed to avoid compliance with the 90-day waiting period limitation. The plan may use a reasonable period of time to determine whether a variable-hour employee is a full-time employee, provided that (a) the period of time is no longer than 12 months; (b) the period of time begins on a date between the employee's start date and the first day of the next calendar month (inclusive); (c) coverage is made effective no later than 13 months from *E*'s start date plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month; and (d) in addition to the measurement period, no more than 90 days elapse prior to the employee's eligibility for coverage.

Example 8. (i) *Facts.* Employee *F* begins working 25 hours per week for Employer *X* on January 6 and is considered a part-time employee for purposes of *X*'s group health plan. *X* sponsors a group health plan that provides coverage to part-time employees after they have completed a cumulative 1,200 hours of service. *F* satisfies the plan's cumulative hours of service condition on December 15.

(ii) *Conclusion.* In this *Example 8*, the cumulative hours of service condition with respect to part-time employees is not considered to be designed to avoid compliance with the 90-day waiting period limitation. Accordingly, coverage for *F* under the plan must begin no later than the 91st day after *F* completes 1,200 hours. (If the plan's cumulative hours-of-service requirement was more than 1,200 hours, the requirement would be considered to be designed to avoid compliance with the 90-day waiting period limitation.)

Example 9. (i) *Facts.* A multiemployer plan operating pursuant to an arms-length collective bargaining agreement has an eligibility provision that allows employees to become eligible for coverage by working a specified number of hours of covered employment for multiple contributing employers. The plan aggregates hours in a calendar quarter and then, if enough hours are earned, coverage begins the first day of the next calendar quarter. The plan also permits coverage to extend for the next full calendar quarter, regardless of whether an employee's employment has terminated.

(ii) *Conclusion.* In this *Example 9*, these eligibility provisions are designed to accommodate a unique operating structure, and, therefore, are not considered to be designed to avoid compliance with the 90- day waiting period limitation, and the plan complies with this section.

Example 10. (i) *Facts.* Employee *G* retires at age 55 after 30 years of employment with Employer *Y* with no expectation of providing further services to Employer *Y*. Three months later, *Y* recruits *G* to return to work as an employee providing advice and transition assistance for *G*'s replacement under a one-year employment contract. *Y*'s plan imposes a 90-day waiting period from an employee's start date before coverage becomes effective.

(ii) *Conclusion.* In this *Example 10*, *Y*'s plan may treat *G* as newly eligible for coverage under the plan upon rehire and therefore may impose the 90-day waiting period with respect to *G* for coverage offered in connection with *G*'s rehire.

Example 11. (i) *Facts.* Employee *H* begins working full time for Employer *Z* on October 16. *Z* sponsors a group health plan, under which full time employees are eligible for coverage after they have successfully completed a bona fide one-month orientation period. *H* completes the orientation period on November 15.

(ii) *Conclusion.* In this *Example 11*, the orientation period is not considered a subterfuge for the passage of time and is not considered to be designed to avoid compliance with the 90-day waiting period limitation. Accordingly, plan coverage for *H* must begin no later than February 14, which is the 91st day after *H* completes the orientation period. (If the orientation period was longer than one month, it would be considered to be a subterfuge for the passage of time and designed to avoid compliance with the 90-day waiting period limitation. Accordingly it would violate the rules of this section.)

(g) *Special rule for health insurance issuers.* To the extent coverage under a group health plan is insured by a health insurance issuer, the issuer is permitted to rely on the eligibility information reported to it by the employer (or other plan sponsor) and will not be considered to violate the requirements of this section with respect to its administration of any waiting period, if both of the following conditions are satisfied:

(1) The issuer requires the plan sponsor to make a representation regarding the terms of any eligibility conditions or waiting periods imposed by the plan sponsor before an individual is eligible to become covered under the terms of the plan (and requires the plan sponsor to update this representation with any changes), and

(2) The issuer has no specific knowledge of the imposition of a waiting period that would exceed the permitted 90-day period.

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any

other provision of State or Federal law (including ERISA, the Code, or other provisions of the Patient Protection and Affordable Care Act). *See e.g.*, § 146.121 of this subchapter and § 147.110, which prohibits discrimination in eligibility for coverage based on a health factor and Code section 4980H, which generally requires applicable large employers to offer coverage to full-time employees and their dependents or make an assessable payment.

(i) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2015. *See* § 147.140 providing that the prohibition on waiting periods exceeding 90 days applies to all group health plans and group health insurance issuers, including grandfathered health plans.

§ 147.120 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example*, the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent*—(1) *In general.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict dependent coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or primary subscriber, or any other person); residency with the participant (in the individual market, the primary subscriber) or with any other person; whether the child lives, works, or resides in an HMO's service area or other network service area; marital status; student status; employment; eligibility for other coverage; or any combination of those factors. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may require coverage of certain children.)

(2) *Construction.* A plan or issuer will not fail to satisfy the requirements of this section if the plan or issuer limits dependent child coverage to children under age 26 who are described in section 152(f)(1) of the Code. For an individual not described in Code section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for dependent child health coverage, such as a condition that the individual be a dependent for income tax purposes.

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

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

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1*, the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3*, the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

Example 4. (i) *Facts.* A group health plan sponsored by a large employer normally charges a copayment for physician visits that do not constitute preventive services. The plan charges this copayment to individuals age 19 and over, including employees, spouses, and dependent children, but waives it for those under age 19.

(ii) *Conclusion.* In this *Example 4*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. While the requirement of paragraph (d) of this section generally prohibits distinctions based upon age in dependent coverage of children, it does not prohibit distinctions based upon age that apply to all coverage under the plan, including coverage for employees and spouses as well as dependent children. In this *Example 4*, the copayments charged to dependent children are the same as those charged to employees and spouses. Accordingly, the arrangement described in this *Example 4* (including waiver, for individuals under age 19, of the generally applicable copayment) does not violate the requirement of paragraph (d) of this section.

(f) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

§ 147.126 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii) and (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) offered through a cafeteria plan pursuant to section 125 of the Internal Revenue Code is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term "essential health benefits" means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations. For the purpose of this section, a group health plan or a health insurance issuer that is not required to provide essential health benefits under

section 1302(b) must define "essential health benefits" in a manner that is consistent with the following:

(1) For plan years beginning before January 1, 2020, one of the EHB-benchmark plans applicable in a State under § 156.110 of this subchapter, and including coverage of any additional required benefits that are considered essential health benefits consistent with § 155.170(a)(2) of this subchapter, or one of the three Federal Employees Health Benefits Program (FEHBP) plan options as defined by § 156.100(a)(3) of this subchapter, supplemented as necessary, to satisfy the standards in § 156.110 of this subchapter; or

(2) For plan years beginning on or after January 1, 2020, an EHB-benchmark plan selected by a State in accordance with the available options and requirements for EHB-benchmark plan selection at § 156.111 of this subchapter, including an EHB-benchmark plan in a State that takes no action to change its EHB-benchmark plan and thus retains the EHB-benchmark plan applicable in that State for the prior year in accordance with § 156.111(d)(1) of this subchapter, and including coverage of any additional required benefits that are considered essential health benefits consistent with § 155.170(a)(2) of this subchapter.

(d) *Health reimbursement arrangements (HRAs) and other account-based group health plans*—(1) *In general.* If an HRA or other account-based group health plan is integrated with another group health plan or individual health insurance coverage and the other group health plan or individual health insurance coverage, as applicable, separately is subject to and satisfies the requirements in PHS Act section 2711 and paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based group health plan are limited does not cause the HRA or other account-based group health plan to fail to satisfy the requirements of PHS Act section 2711 and paragraph (a)(2) of this section. Similarly, if an HRA or other account-based group health plan is integrated with another group health plan or individual health insurance coverage and the other group health plan or individual health insurance coverage, as applicable, separately is subject to and satisfies the requirements in PHS Act section 2713 and § 147.130(a)(1) of this subchapter, the fact that the benefits under the HRA or other account-based group health plan are limited does not cause the HRA or other account-based group health plan to fail to satisfy the requirements of PHS Act section 2713 and § 147.130(a)(1) of this subchapter. For the purpose of this paragraph (d), all individual health insurance coverage, except for coverage that consists solely of excepted benefits, is treated as being subject to and complying with PHS Act sections 2711 and 2713.

(2) *Requirements for an HRA or other account-based group health plan to be integrated with another group health plan.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of PHS Act section 2711 and paragraph (a)(2) of this section if it satisfies the requirements under one of the integration methods set forth in paragraph (d)(2)(i) or (ii) of this section. For purposes of the integration methods under which an HRA or other account-based group health plan is integrated with another group health plan, integration does not require that the HRA or other account-based group health plan and the other group health plan with which it is integrated share the same plan sponsor, the same plan document or governing instruments, or file a single Form 5500, if applicable. An HRA or other account-based group health plan integrated with another group health plan for purposes of PHS Act section 2711 and paragraph (a)(2) of this section may not be used to purchase individual health insurance coverage unless that coverage consists solely of excepted benefits, as defined in § 148.220 of this subchapter.

(i) *Method for integration with a group health plan: Minimum value not required.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of this paragraph (d) if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan) to the employee that does not consist solely of excepted benefits;

(B) The employee receiving the HRA or other account-based group health plan is actually enrolled in a group health plan (other than the HRA or other account-based group health plan) that does not consist solely of excepted benefits,

regardless of whether the plan is offered by the same plan sponsor (referred to as non-HRA group coverage);

(C) The HRA or other account-based group health plan is available only to employees who are enrolled in non- HRA group coverage, regardless of whether the non-HRA group coverage is offered by the plan sponsor of the HRA or other account-based group health plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA group coverage, such as a group health plan maintained by the employer of the employee's spouse);

(D) The benefits under the HRA or other account-based group health plan are limited to reimbursement of one or more of the following—co-payments, coinsurance, deductibles, and premiums under the non-HRA group coverage, as well as medical care expenses that do not constitute essential health benefits as defined in paragraph (c) of this section; and

(E) Under the terms of the HRA or other account-based group health plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based group health plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan (see paragraph (d)(3) of this section for additional rules regarding forfeiture and waiver).

(ii) *Method for integration with another group health plan: Minimum value required.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of this paragraph (d) if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan) to the employee that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Code (and its implementing regulations and applicable guidance);

(B) The employee receiving the HRA or other account-based group health plan is actually enrolled in a group health plan (other than the HRA or other account-based group health plan) that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Code (and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based group health plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based group health plan is available only to employees who are actually enrolled in non-HRA MV group coverage, regardless of whether the non-HRA MV group coverage is offered by the plan sponsor of the HRA or other account-based group health plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA MV group coverage, such as a group health plan maintained by an employer of the employee's spouse); and

(D) Under the terms of the HRA or other account-based group health plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based group health plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan (see paragraph (d)(3) of this section for additional rules regarding forfeiture and waiver).

(3) *Forfeiture.* For purposes of integration under paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section, forfeiture or waiver occurs even if the forfeited or waived amounts may be reinstated upon a fixed date, a participant's death, or the earlier of the two events (the reinstatement event). For the purpose of this paragraph (d)(3), coverage under an HRA or other account-based group health plan is considered forfeited or waived prior to a reinstatement event only if the participant's election to forfeit or waive is irrevocable, meaning that, beginning on the effective date of the election and through the date of the reinstatement event, the participant and the participant's beneficiaries have no access to amounts credited to the HRA or other account-based group health plan. This means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based group health plan may not be used to reimburse or pay medical care expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *Requirements for an HRA or other account-based group health plan to be integrated with individual health insurance coverage or Medicare Part A and B or Medicare Part C.* An HRA or other account-based group health plan is integrated with individual health insurance coverage or Medicare Part A and B or Medicare Part C (and treated as complying with PHS Act sections 2711 and 2713) if the HRA or other account-based group health plan satisfies the requirements of § 146.123(c) of this subchapter (as modified by § 146.123(e), for HRAs or other account-based group health plans integrated with Medicare Part A and B or Medicare Part C).

(5) *Integration with Medicare Part B and D.* For employers that are not required to offer their non-HRA group health plan coverage to employees who are Medicare beneficiaries, an HRA or other account-based group health plan that may be used to reimburse premiums under Medicare Part B or D may be integrated with Medicare (and deemed to comply with PHS Act sections 2711 and 2713) if the following requirements are satisfied with respect to employees who would be eligible for the employer's non-HRA group health plan but for their eligibility for Medicare (and the integration rules under paragraphs (d)(2)(i) and (ii) of this section continue to apply to employees who are not eligible for Medicare):

(i) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan and that does not consist solely of excepted benefits) to employees who are not eligible for Medicare;

(ii) The employee receiving the HRA or other account-based group health plan is actually enrolled in Medicare Part B or D;

(iii) The HRA or other account-based group health plan is available only to employees who are enrolled in Medicare Part B or D; and

(iv) The HRA or other account-based group health plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Definitions.* The following definitions apply for purposes of this section.

(i) *Account-based group health plan.* An account-based group health plan is an employer-provided group health plan that provides reimbursements of medical care expenses with the reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based group health plan. An account-based group health plan does not include a qualified small employer health reimbursement arrangement, as defined in section 9831(d)(2) of the Code.

(ii) *Medical care expenses.* Medical care expenses means expenses for medical care as defined under section 213(d) of the Code.

(e) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2020. Until the applicability date for this section, plans and issuers are required to continue to comply with the corresponding sections of this subchapter B, contained in the 45 CFR, subtitle A, parts 1–199, revised as of October 1, 2018.

§ 147.128 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an

individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if —

(i) The cancellation or discontinuance of coverage has only a prospective effect;

(ii) The cancellation or discontinuance of coverage is effective retroactively, to the extent it is attributable to a failure to timely pay required premiums or contributions (including COBRA premiums) towards the cost of coverage;

(iii) The cancellation or discontinuance of coverage is initiated by the individual (or by the individual's authorized representative) and the sponsor, employer, plan, or issuer does not, directly or indirectly, take action to influence the individual's decision to cancel or discontinue coverage retroactively or otherwise take any adverse action or retaliate against, interfere with, coerce, intimidate, or threaten the individual; or

(iv) The cancellation or discontinuance of coverage is initiated by the Exchange pursuant to § 155.430 of this subchapter (other than under paragraph (b)(2)(iii) of this section).

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

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A's* prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146 of this subchapter. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A's* visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1,* the plan cannot rescind *A's* coverage because *A's* failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B.* After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B's* coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2,* the plan cannot rescind *B's* coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health

insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

§ 147.130 Coverage of preventive health services.

(a) *Services*—(1) *In general*. Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131, 147.132, and 147.133 a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131, 147.132, and 147.133; and

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID–19) and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual

encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

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

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers*—(i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service

in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *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, except as provided in paragraph (b)(3) of this section.

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the applicable plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, is downgraded to a "D" rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a Federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the applicable plan or policy year.

(3) *Rapid coverage of preventive services for coronavirus.* In the case of a qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, a plan or issuer must provide coverage for such item, service, or immunization in accordance with this section by the date that is 15 business days after the date on which a recommendation specified in paragraph (a)(1)(v)(A) or (B) of this section is made relating to such item, service, or immunization.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

(e) *Sunset date*. The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, as a result of COVID–19, including any subsequent renewals of that determination.

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)—(b) [Reserved]

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

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii) or 45 C.F.R. § 147.133(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under §§ 147.132(a) or 147.133, the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after January 14, 2019, if contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(d) *Optional accommodation—insured group health plans*—(1) *General rule*. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in §§ 147.132 or 147.133 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole

responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in §§ 147.132 or 147.133 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in §§ 147.132 or 147.133 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services - insured group health plans and student health insurance coverage*. For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with

enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e): "Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer]."

(f) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(g) *Definition*. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(h) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities*. (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition*. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities*. (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 147.140. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted

under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an "adverse benefit determination" includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony

as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants, beneficiaries and enrollees, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under

this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*—(*1*) In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A

plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(3) *Requirements for individual health insurance issuers.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of this paragraph (b)(3).

(i) *Minimum internal claims and appeals standards.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of the ERISA internal claims and appeals procedures applicable to group health plans under 29 CFR 2560.503–1 except for the requirements with respect to multiemployer plans, and except to the extent those requirements are modified by paragraph (b)(3)(ii) of this section. Accordingly, under this paragraph (b), with respect to individual health insurance coverage, the issuer is subject to the requirements in 29 CFR 2560.503–1 as if the issuer were a group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(3)(i) of this section, the internal claims and appeals processes of a health insurance issuer offering individual health insurance coverage must meet the requirements of this paragraph (b)(3)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(3), an adverse benefit determination includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as other provisions of this paragraph (b)(3), an issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) and any decision to deny coverage in an initial eligibility determination as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the issuer's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* An issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503– 1(h)(2)—

(*1*) The issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the issuer (or at the direction of the issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date

on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the issuer shall notify the claimant of the issuer's determination as soon as an issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) Avoiding conflicts of interest. In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* An issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The issuer must also comply with the additional requirements of this paragraph (b)(3)(ii)(E).

(*1*) The issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the name of the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals

with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the case of an issuer that fails to adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(3)(ii)(F)(*2*) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under State law, as applicable, on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(*2*) Notwithstanding paragraph (b)(3)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the issuer demonstrates that the violation was for good cause or due to matters beyond the control of the issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the issuer and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the issuer. The claimant may request a written explanation of the violation from the issuer, and the issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(3)(ii)(F)(*1*) of this section on the basis that the issuer met the standards for the exception under this paragraph (b)(3)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the issuer shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(G) *One level of internal appeal.* Notwithstanding the requirements in 29 CFR 2560.503–1(c)(3), a health insurance issuer offering individual health insurance coverage must provide for only one level of internal appeal before issuing a final determination.

(H) *Recordkeeping requirements.* A health insurance issuer offering individual health insurance coverage must maintain for six years records of all claims and notices associated with the internal claims and appeals process, including the information detailed in paragraph (b)(3)(ii)(E) of this section and any other information specified by the Secretary. An issuer must make such records available for examination by the claimant or State or Federal oversight agency upon request.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* An issuer subject to the requirements of this paragraph (b)(3) is required to provide continued coverage pending the outcome of an appeal. For this purpose, the issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii) as if the issuer were a group health plan, so that the issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group or individual health insurance

coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section); or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received

emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant, beneficiary, or enrollee is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of PHS Act section 2726 and §§ 146.136 and 147.160, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant, beneficiary, or enrollee fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130; and

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

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

Example 1. (i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1*, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of- network.

(ii) *Conclusion.* In this *Example 2*, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of- network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

Example 3. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency

department of a hospital. The group health plan determines that protections for emergency services under § 149.110 do not apply because the treatment did not involve "emergency services" within the meaning of § 149.110(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3*, the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with § 149.110. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 4. (i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under § 149.120. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of § 149.120.

(ii) *Conclusion.* In this *Example 4*, whether the plan was required to decide the claim in a manner consistent with the requirements of § 149.120 involves considering whether the plan complied with § 149.120, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5. (i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under § 149.110(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with § 149.110.

(ii) *Conclusion.* In this *Example 5*, whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under § 149.110(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6. (i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under § 149.120(a) and the fact that those protections may not be waived for neonatology services under § 149.120(b).

(ii) *Conclusion.* In this *Example 6*, medical judgment is necessary to determine whether the correct code was used and compliance with § 149.120(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7. (i) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under § 149.120(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under § 149.120(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with § 149.120(a) and (b).

(ii) *Conclusion.* In this *Example 7*, consideration of whether the plan complied with the requirements in § 149.120(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately.

Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2)) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.,* worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization.* (A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for

selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(iv) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions

reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section and a self-insured nonfederal governmental plan may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the Federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements*—(i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans and grandfathered individual market policies, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 147.138 Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary,

or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

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

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A's* child. *B* is a participating provider in the HMO's network and is available to accept the child.

(ii) *Conclusion.* In this *Example 1,* the HMO must permit *A's* designation of *B* as the primary care provider for *A's* child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *A* takes *A's* child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A's* child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A's* coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each

participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

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

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A's* designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A's* primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C*, an out-of-network provider.

(ii) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A's* designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or

gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount at least equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (B), and (C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount),

excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of- network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Special rules regarding out-of-network minimum payment standards*—(A) The minimum payment standards set forth under paragraph (b)(3) of this section do not apply in cases where State law prohibits a participant, beneficiary, or enrollee from being required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer provides in benefits, or where a group health plan or health insurance issuer is contractually responsible for such amounts. Nonetheless, in such cases, a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in network.

(B) A group health plan and health insurance issuer must provide a participant, beneficiary, or enrollee adequate and prominent notice of their lack of financial responsibility with respect to the amounts described under this paragraph (b)(3)(iii), to prevent inadvertent payment by the participant, beneficiary, or enrollee.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1,* the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2*, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3*, the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3*. Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4*, the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4.* An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5*, the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services— $116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5*. The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6*, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize*, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning before January 1, 2022. *See also* subparts B and D of part 149 of this subchapter for rules applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage* means coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage. Accordingly, if any benefit package relinquishes grandfather status, it will not affect the grandfather status of the other benefit packages.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

(2) *Disclosure of grandfather status*—(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act, and must provide contact information for questions and complaints, in any summary of benefits provided under the plan.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a "grandfathered health plan" under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that

law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime dollar limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1–866–444–3272 or *www.dol.gov/ebsa/ healthreform*. This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at *www.healthcare.gov*.]

(3)(i) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(A) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(B) Make such records available for examination upon request.

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual dollar limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) *Allowance for new employees to join current plan*—(1) *In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010. Further, the addition of a new contributing employer or new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfather status.

(2) *Anti-abuse rules*—(i) *Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the

employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(iii) *Illustrative list of bona fide employment-based reasons.* For purposes of this paragraph (b)(2)(ii)(C), bona fide employment-based reasons include—

(A) When a benefit package is being eliminated because the issuer is exiting the market;

(B) When a benefit package is being eliminated because the issuer no longer offers the product to the employer;

(C) When low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package;

(D) When a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or

(E) When a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.

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

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *F* and *G*. During a subsequent open enrollment period, some of the employees enrolled in Option *F* on March 23, 2010 switch to Option *G*.

(ii) *Conclusion.* In this *Example 1*, the group health coverage provided under Option *G* remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option *F* are allowed to enroll in Option *G* as new employees.

Example 2. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *H* and *I*. On March 23, 2010, Option *H* provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option *H* and the employees that are moved are transferred to Option *I*. If instead of transferring employees from Option *H* to Option *I*, Option *H* was amended to match the terms of Option *I*, then Option *H* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2*, the plan has a bona fide employment-based reason to transfer employees from Option *H* to Option *I*. Therefore, Option *I* does not cease to be a grandfathered health plan.

(c) *General grandfathering rule*—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual dollar limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime dollar limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans—In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraphs (g)(2) and (3) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. A plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms that results in a change described in this paragraph (g)(1) becomes effective, regardless of when the amendment was adopted. Once grandfather status is lost, it cannot be regained.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition. Whether or not a plan or coverage has eliminated substantially all benefits to diagnose or treat a particular condition must be determined based on all the facts and circumstances, taking into account the items and services provided for a particular condition under the plan on March 23, 2010, as compared to the benefits offered at the time the plan or coverage makes the benefit change effective.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, and determined for each copayment level if a plan has different copayment levels for different categories of services, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(4)(i) of this section (that is, $5 times medical inflation, plus $5); or

(B) The maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage*. A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(4)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(4)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group or individual health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. (But see § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* Grandfathered individual health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. (*But see* § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in

the individual market, policy years) beginning on or after January 1, 2014).

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits). (*But see* § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Special rule for certain grandfathered high deductible health plans.* With respect to a grandfathered group health plan or group health insurance coverage that is a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, increases to fixed-amount cost-sharing requirements made effective on or after June 15, 2021 that otherwise would cause a loss of grandfather status will not cause the plan or coverage to relinquish its grandfather status, but only to the extent such increases are necessary to maintain its status as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

(4) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor using the 1982– 1984 base

of 100. For purposes of this paragraph (g)(4)(i), the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means:

(A) With respect to increases for a group health plan and group health insurance coverage made effective on or after March 23, 2010, and before June 15, 2021, medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points;

(B) With respect to increases for a group health plan and group health insurance coverage made effective on or after June 15, 2021, the greater of:

(*1*) Medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points; or

(*2*) The portion of the premium adjustment percentage, as defined in § 156.130(e) of this subchapter, that reflects the relative change between 2013 and the calendar year prior to the effective date of the increase (that is, the premium adjustment percentage minus 1), expressed as a percentage, plus 15 percentage points; and

(C) With respect to increases for individual health insurance coverage, medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

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

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40, effective before June 15, 2021. Within the 12- month period before the $40 copayment takes

effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3*, the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40-30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2269 (475-387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3* of this paragraph (g)(5), except the grandfathered group health plan subsequently increases the $40 copayment requirement to $45 for a later plan year, effective before June 15, 2021. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4*, the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45-30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2527 (485-387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 (5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* Same facts as *Example 4* of this paragraph (g)(5), except the grandfathered group health plan increases the copayment requirement to $45, effective *after* June 15, 2021. The greatest value of the overall medical care component of the CPI–U (unadjusted) in the preceding 12-month period is still 485. In the calendar year that includes the effective date of the increase, the applicable portion of the premium adjustment percentage is 36%.

(ii) *Conclusion.* In this *Example 5*, the grandfathered health plan may increase the copayment by the greater of: Medical inflation, expressed as a percentage, plus 15 percentage points; or the applicable portion of the premium adjustment percentage for the calendar year that includes the effective date of the increase, plus 15 percentage points. The latter amount is greater because it results in a 51% maximum percentage increase (36% + 15% = 51%) and, as demonstrated in *Example 4* of this paragraph (g)(5), determining the maximum percentage increase using medical inflation yields a result of 40.27%. The increase in the copayment, expressed as a percentage, is 50% (45-30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Because the 50% increase in the copayment is less than the 51% maximum percentage increase, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 6. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15, effective before June 15, 2021. Within the 12- month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 6*, the increase in the copayment, expressed as a percentage, is 50% (15-10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0-387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a group plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20%), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to $5.36.

Example 7. (i) *Facts.* Same facts as *Example 6* of this paragraph (g)(5), except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently, amended to increase the copayment requirement to $5, effective before June 15, 2021.

(ii) *Conclusion.* In this *Example 7*, medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0-387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 7* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer

reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 8*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 9. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5,000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1,000 for self-only coverage and $4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5,000-1,000)/5,000) for self-only coverage and 67% ((12,000-4,000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6,000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1,200 for self-only coverage and $5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6,000-1,200)/6,000) for self-only coverage and 67% ((15,000-5,000)/ 15,000) for family coverage.

(ii) *Conclusion.* In this *Example 9*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 10. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 10*, the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

Example 11. (i) *Facts.* A group health plan that is a grandfathered health plan and also a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code had a $2,400 deductible for family coverage on March 23, 2010. The plan is subsequently amended after June 15, 2021 to increase the deductible limit by the amount that is necessary to comply with the requirements for a plan to qualify as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code, but that exceeds the maximum percentage increase.

(ii) *Conclusion.* In this *Example 11*, the increase in the deductible at that time does not cause the plan to cease to be a grandfathered health plan because the increase was necessary for the plan to continue to satisfy the definition of a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

§ 147.145 Student health insurance coverage.

(a) *Definition.* Student health insurance coverage is a type of individual health insurance coverage (as defined in § 144.103 of this subchapter) that is provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students enrolled in that institution of higher education and their dependents, that meets the following conditions:

(1) Does not make health insurance coverage available other than in connection with enrollment as a student (or as a dependent of a student) in the institution of higher education.

(2) Does not condition eligibility for the health insurance coverage on any health status-related factor (as defined in § 146.121(a) of this subchapter) relating to a student (or a dependent of a student).

(3) Meets any additional requirement that may be imposed under State law.

(b) *Exemptions from the Public Health Service Act and the Affordable Care Act*—(1) *Guaranteed availability and guaranteed renewability*—(i) For purposes of sections 2741(e)(1) and 2742(b)(5) of the Public Health Service Act, student health insurance coverage is deemed to be available only through a bona fide association.

(ii) For purposes of section 2702 of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not required to accept individuals who are not students or dependents of students in such coverage, and, notwithstanding the requirements of §147.104(b), is not required to establish open enrollment periods or coverage effective dates that are based on a calendar policy year or to offer policies on a calendar year basis.

(iii) For purposes of section 2703(a) of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not required to renew or continue in force coverage for individuals who are no longer students or dependents of students.

(2) *Levels of coverage*. The requirement to provide a specific level of coverage described in section 1302(d) of the Affordable Care Act does not apply to student health insurance coverage for policy years beginning on or after July 1, 2016. However, the benefits provided by such coverage must provide at least 60 percent actuarial value, as calculated in accordance with §156.135 of this subchapter. The issuer must specify in any plan materials summarizing the terms of the coverage the actuarial value and level of coverage (or next lowest level of coverage) the coverage would otherwise satisfy under §156.140 of this subchapter.

(3) *Single risk pool*. Student health insurance coverage is not subject to the requirements of section 1312(c) of the Affordable Care Act. A health insurance issuer that offers student health insurance coverage may establish one or more separate risk pools for an institution of higher education, if the distinction between or among groups of students (or dependents of students) who form the risk pool is based on a bona fide school-related classification and not based on a health factor (as described in §146.121 of this subchapter). However, student health insurance rates must reflect the claims experience of individuals who comprise the risk pool, and any adjustments to rates within a risk pool must be actuarially justified.

(c) *Student administrative health fees.* (1) *Definition.* A student administrative health fee is a fee charged by the institution of higher education on a periodic basis to students of the institution of higher education to offset the cost of providing health care through health clinics regardless of whether the students utilize the health clinics or enroll in student health insurance coverage.

(2) *Preventive services.* Notwithstanding the requirements under section 2713 of the Public Health Service Act and its implementing regulations, student administrative health fees as defined in paragraph (c)(1) of this section are not considered cost-sharing requirements with respect to specified recommended preventive services.

§ 147.150 Coverage of essential health benefits.

(a) *Requirement to cover the essential health benefits package.* A health insurance issuer offering health insurance coverage in the individual or small group market must ensure that such coverage includes the essential health benefits package as defined in section 1302(a) of the Affordable Care Act effective for plan or policy years beginning on or after January 1, 2014.

(b) *Cost-sharing under group health plans.* [Reserved.]

(c) *Child-only plans.* If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d)(1) of the Affordable Care Act, the issuer must offer coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

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

(a) *In general.* The provisions of § 146.136 of this subchapter apply to health insurance coverage offered by health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after the applicability dates set forth in § 146.136(i) of this subchapter. This section applies to non-grandfathered and grandfathered health plans as defined in § 147.140.

§ 147.200 Summary of benefits and coverage and uniform glossary.

(a) *Summary of benefits and coverage*—(1) *In general.* A group health plan (and its administrator as defined in section 3(16)(A) of ERISA)), and a health insurance issuer offering group or individual health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for each benefit package without charge to entities and

individuals described in this paragraph (a)(1) in accordance with the rules of this section.

(i) *SBC provided by a group health insurance issuer to a group health plan*—(A) *Upon application.* A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application for health coverage, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application. If an SBC was provided before application pursuant to paragraph (a)(1)(i)(D) of this section (relating to SBCs upon request), this paragraph (a)(1)(i)(A) is deemed satisfied, provided there is no change to the information required to be in the SBC. However, if there has been a change in the information required, a new SBC that includes the changed information must be provided upon application pursuant to this paragraph (a)(1)(i)(A).

(B) *By first day of coverage (if there are changes).* If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the plan (or its sponsor) no later than the first day of coverage.

(C) *Upon renewal, reissuance, or reenrollment.* If the issuer renews or reissues a policy, certificate, or contract of insurance for a succeeding policy year, or automatically re-enrolls the policyholder or its participants and beneficiaries in coverage, the issuer must provide a new SBC as follows:

(*1*) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date the written application materials are distributed.

(*2*) If renewal, reissuance, or reenrollment is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year; however, with respect to an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) *Upon request.* If a group health plan (or its sponsor) requests an SBC or summary information about a health insurance product from a health insurance issuer offering group health insurance coverage, an SBC must be provided as soon as practicable, but in no event later than seven business days following receipt of the request.

(ii) *SBC provided by a group health insurance issuer and a group health plan to participants and beneficiaries*—

(A) *In general.* A group health plan (including its administrator, as defined under section 3(16) of ERISA), and a health insurance issuer offering group health insurance coverage, must provide an SBC to a participant or beneficiary (as defined under sections 3(7) and 3(8) of ERISA), and consistent with the rules of paragraph (a)(1)(iii) of this section, with respect to each benefit package offered by the plan or issuer for which the participant or beneficiary is eligible.

(B) *Upon application.* The SBC must be provided as part of any written application materials that are distributed by the plan or issuer for enrollment. If the plan or issuer does not distribute written application materials for enrollment, the SBC must be provided no later than the first date on which the participant is eligible to enroll in coverage for the participant or any beneficiaries. If an SBC was provided before application pursuant to paragraph (a)(1)(ii)(F) of this section (relating to SBCs upon request), this paragraph (a)(1)(ii)(B) is deemed satisfied, provided

there is no change to the information required to be in the SBC. However, if there has been a change in the information that is required to be in the SBC, a new SBC that includes the changed information must be provided upon application pursuant to this paragraph (a)(1)(ii)(B).

(C) *By first day of coverage (if there are changes).* (*1*) If there is any change to the information required to be in the SBC that was provided upon application and before the first day of coverage, the plan or issuer must update and provide a current SBC to a participant or beneficiary no later than the first day of coverage.

(*2*) If the plan sponsor is negotiating coverage terms after an application has been filed and the information required to be in the SBC changes, the plan or issuer is not required to provide an updated SBC (unless an updated SBC is requested) until the first day of coverage.

(D) *Special enrollees.* The plan or issuer must provide the SBC to special enrollees (as described in § 146.117 of this subchapter) no later than the date by which a summary plan description is required to be provided under the timeframe set forth in ERISA section 104(b)(1)(A) and its implementing regulations, which is 90 days from enrollment.

(E) *Upon renewal, reissuance, or reenrollment.* If the plan or issuer requires participants or beneficiaries to renew in order to maintain coverage (for example, for a succeeding plan year), or automatically re-enrolls participants and beneficiaries in coverage, the plan or issuer must provide a new SBC, as follows:

(*1*) If written application is required for renewal, reissuance, or reenrollment (in either paper or electronic form), the SBC must be provided no later than the date on which the written application materials are distributed.

(*2*) If renewal, reissuance, or reenrollment is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year; however, with respect to an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(F) *Upon request.* A plan or issuer must provide the SBC to participants or beneficiaries upon request for an SBC or summary information about the health coverage, as soon as practicable, but in no event later than seven business days following receipt of the request.

(iii) *Special rules to prevent unnecessary duplication with respect to group health coverage*—(A) An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual satisfies that requirement if another party provides the SBC, but only to the extent that the SBC is timely and complete in accordance with the other rules of this section. Therefore, for example, in the case of a group health plan funded through an insurance policy, the plan satisfies the requirement to provide an SBC with respect to an individual if the issuer provides a timely and complete SBC to the individual. An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual that contracts with another party to provide such SBC is considered to satisfy the requirement to provide such SBC if:

(*1*) The entity monitors performance under the contract;

(*2*) If the entity has knowledge that the SBC is not being provided in a manner that satisfies the requirements of this section and the entity has all information necessary to correct the

noncompliance, the entity corrects the noncompliance as soon as practicable; and

(*3*) If the entity has knowledge the SBC is not being provided in a manner that satisfies the requirements of this section and the entity does not have all information necessary to correct the noncompliance, the entity communicates with participants and beneficiaries who are affected by the noncompliance regarding the noncompliance, and begins taking significant steps as soon as practicable to avoid future violations.

(B) If a single SBC is provided to a participant and any beneficiaries at the participant's last known address, then the requirement to provide the SBC to the participant and any beneficiaries is generally satisfied. However, if a beneficiary's last known address is different than the participant's last known address, a separate SBC is required to be provided to the beneficiary at the beneficiary's last known address.

(C) With respect to a group health plan that offers multiple benefit packages, the plan or issuer is required to provide a new SBC automatically to participants and beneficiaries upon renewal or reenrollment only with respect to the benefit package in which a participant or beneficiary is enrolled (or will be automatically re-enrolled under the plan); SBCs are not required to be provided automatically upon renewal or reenrollment with respect to benefit packages in which the participant or beneficiary is not enrolled (or will not automatically be enrolled). However, if a participant or beneficiary requests an SBC with respect to another benefit package (or more than one other benefit package) for which the participant or beneficiary is eligible, the SBC (or SBCs, in the case of a request for SBCs relating to more than one benefit package) must be provided upon request as soon as practicable, but in no event later than seven business days following receipt of the request.

(D) Subject to paragraph (a)(2)(ii) of this section, a plan administrator of a group health plan that uses two or more insurance products provided by separate health insurance issuers with respect to a single group health plan may synthesize the information into a single SBC or provide multiple partial SBCs provided that all the SBC include the content in paragraph (a)(2)(iii) of this section.

(iv) *SBC provided by a health insurance issuer offering individual health insurance coverage*—(A) *Upon application.* A health insurance issuer offering individual health insurance coverage must provide an SBC to an individual covered under the policy (including every dependent) upon receiving an application for any health insurance policy, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application. If an SBC was provided before application pursuant to paragraph (a)(1)(iv)(D) of this section (relating to SBCs upon request), this paragraph (a)(1)(iv)(A) is deemed satisfied, provided there is no change to the information required to be in the SBC. However, if there has been a change in the information that is required to be in the SBC, a new SBC that includes the changed information must be provided upon application pursuant to this paragraph (a)(1)(iv)(A).

(B) *By first day of coverage (if there are changes).* If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the individual no later than the first day of coverage.

(C) *Upon renewal, reissuance, or reenrollment.* If the issuer renews or reissues a policy, certificate, or contract of insurance for a succeeding policy year, or automatically re-enrolls an individual (or dependent) covered under a policy,

certificate, or contract of insurance into a policy, certificate, or contract of insurance under a different plan or product, the issuer must provide an SBC for the coverage in which the individual (including every dependent) will be enrolled, as follows:

(*1*) If written application is required (in either paper or electronic form) for renewal, reissuance, or reenrollment, the SBC must be provided no later than the date on which the written application materials are distributed.

(*2*) If renewal, reissuance, or reenrollment is automatic, the SBC must be provided no later than 30 days prior to the first day of the new policy year; however, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30 day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) *Upon request.* A health insurance issuer offering individual health insurance coverage must provide an SBC to any individual or dependent upon request for an SBC or summary information about a health insurance product as soon as practicable, but in no event later than seven business days following receipt of the request.

(v) *Special rule to prevent unnecessary duplication with respect to individual health insurance coverage—*

(A) *In general.* If a single SBC is provided to an individual and any dependents at the individual's last known address, then the requirement to provide the SBC to the individual and any dependents is generally satisfied. However, if a dependent's last known address is different than the individual's last known address, a separate SBC is required to be provided to the dependent at the dependents' last known address.

(B) *Student health insurance coverage.* With respect to student health insurance coverage as defined at § 147.145(a), the requirement to provide an SBC to an individual will be considered satisfied for an entity if another party provides a timely and complete SBC to the individual. An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual that contracts with another party to provide such SBC is considered to satisfy the requirement to provide such SBC if:

(*1*) The entity monitors performance under the contract;

(*2*) If the entity has knowledge that the SBC is not being provided in a manner that satisfies the requirements of this section and the entity has all information necessary to correct the noncompliance, the entity corrects the noncompliance as soon as practicable; and

(*3*) If the entity has knowledge the SBC is not being provided in a manner that satisfies the requirements of this section and the entity does not have all information necessary to correct the noncompliance, the entity communicates with covered individuals and dependents who are affected by the noncompliance regarding the noncompliance, and begins taking significant steps as soon as practicable to avoid future violations.

(2) *Content*—(i) *In general.* Subject to paragraph (a)(2)(iii) of this section, the SBC must include the following:

(A) Uniform definitions of standard insurance terms and medical terms so that consumers may compare health coverage and understand the terms of (or exceptions to) their coverage, in accordance with guidance as specified by the Secretary;

(B) A description of the coverage, including cost sharing, for each category of benefits identified by the Secretary in guidance;

(C) The exceptions, reductions, and limitations of the coverage;

(D) The cost-sharing provisions of the coverage, including deductible, coinsurance, and copayment obligations;

(E) The renewability and continuation of coverage provisions;

(F) Coverage examples, in accordance with the rules of paragraph (a)(2)(ii) of this section;

(G) With respect to coverage beginning on or after January 1, 2014, a statement about whether the plan or coverage provides minimum essential coverage as defined under section 5000A(f) and whether the plan's or coverage's share of the total allowed costs of benefits provided under the plan or coverage meets applicable requirements;

(H) A statement that the SBC is only a summary and that the plan document, policy, certificate, or contract of insurance should be consulted to determine the governing contractual provisions of the coverage;

(I) Contact information for questions;

(J) For issuers, an Internet web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained;

(K) For plans and issuers that maintain one or more networks of providers, an Internet address (or similar contact information) for obtaining a list of network providers;

(L) For plans and issuers that use a formulary in providing prescription drug coverage, an Internet address (or similar contact information) for obtaining information on prescription drug coverage;

(M) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section, as well as a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies are available; and

(N) For qualified health plans sold through an individual market Exchange that exclude or provide for coverage of the services described in § 156.280(d)(1) or (2) of this subchapter, a notice of coverage or exclusion of such services.

(ii) *Coverage examples.* The SBC must include coverage examples specified by the Secretary in guidance that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) in accordance with this paragraph (a)(2)(ii).

(A) *Number of examples.* The Secretary may identify up to six coverage examples that may be required in an SBC.

(B) *Benefits scenarios.* For purposes of this paragraph (a)(2)(ii), a benefits scenario is a hypothetical situation, consisting of a sample treatment plan for a specified medical condition during a specific period of time, based on recognized clinical practice guidelines as defined by the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the assumptions, including the relevant items and services and reimbursement information, for each claim in the benefits scenario.

(C) *Illustration of benefit provided.* For purposes of this paragraph (a)(2)(ii), to illustrate benefits provided under the plan or coverage for a particular benefits scenario, a plan or issuer simulates claims processing in accordance with guidance issued by the Secretary to generate an estimate of what an individual might expect to pay under the plan, policy, or benefit package. The illustration of

benefits provided will take into account any cost sharing, excluded benefits, and other limitations on coverage, as specified by the Secretary in guidance.

(iii) *Coverage provided outside the United States.* In lieu of summarizing coverage for items and services provided outside the United States, a plan or issuer may provide an Internet address (or similar contact information) for obtaining information about benefits and coverage provided outside the United States. In any case, the plan or issuer must provide an SBC in accordance with this section that accurately summarizes benefits and coverage available under the plan or coverage within the United States.

(3) *Appearance.* (i) A group health plan and a health insurance issuer must provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance. The SBC must be presented in a uniform format, use terminology understandable by the average plan enrollee (or, in the case of individual market coverage, the average individual covered under a health insurance policy), not exceed four double-sided pages in length, and not include print smaller than 12-point font. A health insurance issuer offering individual health insurance coverage must provide the SBC as a stand-alone document.

(ii) A group health plan that utilizes two or more benefit packages (such as major medical coverage and a health flexible spending arrangement) may synthesize the information into a single SBC, or provide multiple SBCs.

(4) *Form.* (i) An SBC provided by an issuer offering group health insurance coverage to a plan (or its sponsor), may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the following three conditions are satisfied—

(A) The format is readily accessible by the plan (or its sponsor);

(B) The SBC is provided in paper form free of charge upon request; and

(C) If the electronic form is an Internet posting, the issuer timely advises the plan (or its sponsor) in paper form or email that the documents are available on the Internet and provides the Internet address.

(ii) An SBC provided by a group health plan or health insurance issuer to a participant or beneficiary may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the requirements of this paragraph (a)(4)(ii) are met.

(A) With respect to participants and beneficiaries covered under the plan or coverage, the SBC may be provided electronically as described in this paragraph (a)(4)(ii)(A). However, in all cases, the plan or issuer must provide the SBC in paper form if paper form is requested.

(*1*) In accordance with the Department of Labor's disclosure regulations at 29 CFR 2520.104b–1;

(*2*) In connection with online enrollment or online renewal of coverage under the plan; or

(*3*) In response to an online request made by a participant or beneficiary for the SBC.

(B) With respect to participants and beneficiaries who are eligible but not enrolled for coverage, the SBC may be provided electronically if:

(*1*) The format is readily accessible;

(*2*) The SBC is provided in paper form free of charge upon request; and

(*3*) In a case in which the electronic form is an Internet posting, the plan or issuer timely notifies the individual in paper form (such as a postcard) or email that the documents are available on the Internet, provides the Internet address, and notifies the individual that

the documents are available in paper form upon request.

(iii) An issuer offering individual health insurance coverage must provide an SBC in a manner that can reasonably be expected to provide actual notice in paper or electronic form.

(A) An issuer satisfies the requirements of this paragraph (a)(4)(iii) if the issuer:

(*1*) Hand-delivers a printed copy of the SBC to the individual or dependent;

(*2*) Mails a printed copy of the SBC to the mailing address provided to the issuer by the individual or dependent;

(*3*) Provides the SBC by email after obtaining the individual's or dependent's agreement to receive the SBC or other electronic disclosures by email;

(*4*) Posts the SBC on the Internet and advises the individual or dependent in paper or electronic form, in a manner compliant with paragraphs (a)(4)(iii)(A)(*1*) through (*3*) of this section, that the SBC is available on the Internet and includes the applicable Internet address; or

(*5*) Provides the SBC by any other method that can reasonably be expected to provide actual notice.

(B) An SBC may not be provided electronically unless:

(*1*) The format is readily accessible;

(*2*) The SBC is placed in a location that is prominent and readily accessible;

(*3*) The SBC is provided in an electronic form which can be electronically retained and printed;

(*4*) The SBC is consistent with the appearance, content, and language requirements of this section;

(*5*) The issuer notifies the individual or dependent that the SBC is available in paper form without charge upon request and provides it upon request.

(C) *Deemed compliance.* A health insurance issuer offering individual health insurance coverage that provides the content required under paragraph (a)(2) of this section, as specified in guidance published by the Secretary, to the federal health reform Web portal described in § 159.120 of this subchapter will be deemed to satisfy the requirements of paragraph (a)(1)(iv)(D) of this section with respect to a request for summary information about a health insurance product made prior to an application for coverage. However, nothing in this paragraph should be construed as otherwise limiting such issuer's obligations under this section.

(iv) An SBC provided by a self-insured non-Federal governmental plan may be provided in paper form. Alternatively, the SBC may be provided electronically if the plan conforms to either the substance of the provisions in paragraph (a)(4)(ii) or (iii) of this section.

(5) *Language.* A group health plan or health insurance issuer must provide the SBC in a culturally and linguistically appropriate manner. For purposes of this paragraph (a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of § 147.136(e) are met as applied to the SBC.

(b) *Notice of modification.* If a group health plan, or health insurance issuer offering group or individual health insurance coverage, makes any material modification (as defined under section 102 of ERISA) in any of the terms of the plan or coverage that would affect the content of the SBC, that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees (or, in the case of individual market coverage, an individual covered under a health insurance policy) not later than 60 days prior to the date on which the modification will become effective. The notice of

modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section.

(c) *Uniform glossary*—(1) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, must make available to participants and beneficiaries, and a health insurance issuer offering individual health insurance coverage must make available to applicants, policyholders, and covered dependents, the uniform glossary described in paragraph (c)(2) of this section in accordance with the appearance and form and manner requirements of paragraphs (c)(3) and (4) of this section.

(2) *Health-coverage-related terms and medical terms.* The uniform glossary must provide uniform definitions, specified by the Secretary in guidance, of the following health-coverage-related terms and medical terms:

(i) Allowed amount, appeal, balance billing, co-insurance, complications of pregnancy, co-payment, deductible, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, in-network coinsurance, in-network co-payment, medically necessary, network, non-preferred provider, out-of-network coinsurance, out-of-network copayment, out-of-pocket limit, physician services, plan, preauthorization, preferred provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, rehabilitation services, skilled nursing care, specialist, usual customary and reasonable (UCR), and urgent care; and

(ii) Such other terms as the Secretary determines are important to define so that individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in guidance.

(3) *Appearance.* A group health plan, and a health insurance issuer, must provide the uniform glossary with the appearance specified by the Secretary in guidance to ensure the uniform glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee (or, in the case of individual market coverage, an average individual covered under a health insurance policy).

(4) *Form and manner.* A plan or issuer must make the uniform glossary described in this paragraph (c) available upon request, in either paper or electronic form (as requested), within seven business days after receipt of the request.

(d) *Preemption.* For purposes of this section, the provisions of section 2724 of the PHS Act continue to apply with respect to preemption of State law. State laws that conflict with this section (including a state law that requires a health insurance issuer to provide an SBC that supplies less information than required under paragraph (a) of this section) are preempted.

(e) *Failure to provide.* A health insurance issuer or a non-federal governmental health plan that willfully fails to provide information to a covered individual required under this section is subject to a fine of not more than $1,000 as adjusted annually under 45 C.F.R. part 102 for each such failure. A failure with respect to each covered individual constitutes a separate offense for purposes of this paragraph (e). HHS will enforce these provisions in a manner consistent with §§ 150.101 through 150.465 of this subchapter.

(f) *Applicability to Medicare Advantage benefits.* The requirements of this section do not apply to a group health plan benefit package that provides Medicare Advantage benefits pursuant to or 42 U.S.C. Chapter 7, Subchapter XVIII, Part C.

(g) *Applicability date.* (1) This section is applicable to group health plans and group health insurance issuers in accordance with this paragraph (g). (See § 147.140(d), providing that this section applies to grandfathered health plans.)

(i) For disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), this section applies beginning on the first day of the first open enrollment period that begins on or after September 1, 2015; and

(ii) For disclosures with respect to participants and beneficiaries who enroll in coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), this section applies beginning on the first day of the first plan year that begins on or after September 1, 2015.

(2) For disclosures with respect to plans, this section is applicable to health insurance issuers beginning September 1, 2015.

(3) For disclosures with respect individuals and covered dependents in the individual market, this section is applicable to health insurance issuers beginning with respect to SBCs issued for coverage that begins on or after January 1, 2016.

§ 147.210 Transparency in coverage - definitions.

(a) *Scope and definitions*--(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers in the individual and group markets established in this section and §§ 147.211 and 147.212.

(2) *Definitions.* For purposes of this section and §§ 147.211 and 147.212, the following definitions apply:

(i) Accumulated amounts means:

(A) The amount of financial responsibility a participant, beneficiary, or enrollee has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant, beneficiary, or enrollee has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant, beneficiary, or enrollee has used within that time period).

(ii) Billed charge means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) Billing code means the code used by a group health plan or health insurance issuer or provider to identify health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(iv) Bundled payment arrangement means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant, beneficiary, or enrollee for a specific treatment or procedure.

(v) Copayment assistance means the financial assistance a participant, beneficiary, or enrollee receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) Cost-sharing liability means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vii) Cost-sharing information means information related to any expenditure required by or on behalf of a participant, beneficiary, or enrollee with respect to health care benefits that are relevant to a determination of the participant's, beneficiary's, or enrollee's cost-sharing liability for a particular covered item or service.

(viii) Covered items or services means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) Derived amount means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers or submitting data in accordance with the requirements of §153.710(c) of this subchapter.

(x) Enrollee means an individual who is covered under an individual health insurance policy as defined under section 2791(b)(5) of the Public Health Service (PHS) Act.

(xi) Historical net price means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with § 147.212. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under § 147.212(b)(1)(iii)(D)(3).

(xii) In-network provider means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee.

(xiii) Items or services means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in connection with the provision of health care.

(xiv) Machine-readable file means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xv) National Drug Code means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xvi) Negotiated rate means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network

provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvii) Out-of-network allowed amount means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xviii) Out-of-network provider means a provider of any item or service that does not have a contract under a participant's, beneficiary's, or enrollee's group health plan or health insurance coverage to provide items or services.

(xix) Out-of-pocket limit means the maximum amount that a participant, beneficiary, or enrollee is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xx) Plain language means written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.

(xxi) Prerequisite means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxii) Underlying fee schedule rate means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

§ 147.211 Transparency in coverage - required disclosures to participants, beneficiaries, or enrollees.

(a) *Scope and definitions*--(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 147.210 apply.

(b) *Required disclosures to participants, beneficiaries, or enrollees*. At the request of a participant, beneficiary, or enrollee who is enrolled in a group health plan or health insurance issuer offering group or individual health insurance coverage, the plan or issuer must provide to the participant, beneficiary, or enrollee the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's, beneficiary's, or enrollee's cost-sharing liability for covered items and services:

(i) An estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for a requested covered item or service furnished by a provider or providers, which must reflect any cost-sharing reductions the enrollee would receive, that is calculated based on the information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health

insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant, beneficiary, or enrollee to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as "preventive", "non-preventive" or "diagnostic" as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant, beneficiary, or enrollee requests information for an item or service subject to a bundled payment arrangement, a list of the items and services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants, beneficiaries, or enrollees for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant, beneficiary, or enrollee in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential additional amounts. This

statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's, beneficiary's, or enrollee's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant, beneficiary, or enrollee receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's, beneficiary's, or enrollee's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants, beneficiaries, or enrollees.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as "rapid flu test"), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's, beneficiary's, or enrollee's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for

covered items or services returns multiple results.

(ii) *Paper method*. Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant, beneficiary, or enrollee. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant, beneficiary, or enrollee;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants, beneficiaries, and enrollees request disclosure other than by paper (for example, by phone or e-mail), plans and issuers may provide the disclosure through another means, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*--(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements*. A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(2) As provided under §147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 147.126(d)(6) or short term limited duration insurance as defined in 45 CFR 144.103.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 147.212 Transparency in coverage - requirements for public disclosure.

(a) *Scope and definitions*--(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions*. For purposes of this section, the definitions in § 147.210 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs*. A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information*. Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14- digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee

schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant, beneficiary, or enrollee-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant, beneficiary, or enrollee-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5- digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC, and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA), for each covered item or service that is a prescription drug under each

coverage option offered by a plan or issuer;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (b)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public*. The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing*. A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements*. A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into

such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts*. Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability*. (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2022.

(2) As provided under § 147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in § 147.126(d)(6) or short term limited duration insurance as defined in § 144.103 of this subchapter.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

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PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–11 300gg–91, and 300–gg92, as amended.

SUBPART A—GENERAL PROVISIONS

§ 148.101 Basis and purpose.

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to guarantee the renewability of all coverage in the individual market. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth and protects all individuals and family members who have, or seek, individual health insurance coverage from discrimination based on genetic information.

§ 148.102 Scope and applicability date.

(a) *Scope and applicability.* (1) Individual health insurance coverage includes all health insurance coverage (as defined in § 144.103 of this subchapter) that is neither health insurance coverage sold in connection with an employment-related group health plan, nor short-term, limited-duration coverage as defined in § 144.103 of this subchapter.

(2) The requirements that pertain to guaranteed renewability for all individuals, to protections for mothers and newborns with respect to hospital stays in connection with childbirth, and to protections against discrimination based on genetic information apply to all issuers of individual health insurance coverage in the State.

(b) *Applicability date.* Except as provided in § 148.124 (certificate of creditable coverage), § 148.170 (standards relating to benefits for mothers and newborns), and § 148.180 (prohibition of health discrimination based on genetic information), the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997. Notwithstanding the previous sentence, the definition of "short-term, limited-duration insurance" in § 144.103 of this subchapter is applicable October 2, 2018.

§ 148.103 [Removed].

SUBPART B—REQUIREMENTS RELATING TO ACCESS AND RENEWABILITY OF COVERAGE

§ 148.120 Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage.

The rules for guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of § 147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

§ 148.122 Guaranteed renewability of individual health insurance coverage.

(a) *Applicability.* This section applies to non-grandfathered and grandfathered health plans (within the meaning of § 147.140 of this subchapter) that are individual health insurance coverage. *See* also § 147.106 of this subchapter for requirements relating to guaranteed renewability of coverage with respect to non-grandfathered health plans.

(b) *General rules.* (1) Except as provided in paragraphs (c) through (g) of this section, an issuer must renew or continue in force the coverage at the option of the individual.

(2) Medicare entitlement or enrollment is not a basis to nonrenew an individual's health insurance coverage in the individual market under the same policy or contract of insurance.

(c) *Exceptions to renewing coverage*. An issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

(1) *Nonpayment of premiums.* The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The individual has performed an act or practice that constitutes fraud or made an

intentional misrepresentation of material fact under the terms of the coverage.

(3) *Termination of product.* The issuer is ceasing to offer coverage in the market in accordance with paragraph (d) or (e) of this section and applicable State law.

(4) *Movement outside the service area.* For network plans, the individual no longer resides, lives, or works in the service area of the issuer, or area for which the issuer is authorized to do business, but only if coverage is terminated uniformly without regard to any health status-related factor of covered individuals; provided the issuer provides notice in accordance with the requirements of paragraph (d)(1) of this section.

(5) *Association membership ceases.* For coverage made available in the individual market only through one or more bona fide associations, the individual's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor of covered individuals.

(d) *Discontinuing a particular type of coverage.* An issuer may discontinue offering a particular type of health insurance coverage offered in the individual market only if it meets the following requirements:

(1) Provides notice in writing, in a form and manner specified by the Secretary, to each individual provided coverage of that type of health insurance at least 90 calendar days before the date the coverage will be discontinued.

(2) Offers to each covered individual, on a guaranteed issue basis, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in that market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(e) *Discontinuing all coverage.* An issuer may discontinue offering all health insurance coverage in the individual market in a State only if it meets the following requirements.

(1) Provides notice in writing to the applicable State authority and to each individual of the discontinuation at least 180 days before the date the coverage will expire.

(2) Discontinues and does not renew all health insurance policies it issues or delivers for issuance in the State in the individual market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(4) For purposes of this paragraph (e), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with § 144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (e)(4)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with § 144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (e)(4)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements

are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (e)(4)(ii)(B) of this section.

(5) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

(f) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage under paragraph (e) of this section may not issue coverage in the market and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(g) *Exception for uniform modification of coverage.* (1) An issuer may, only at the time of coverage renewal, modify the health insurance coverage for a product offered in the individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

(2) For purposes of paragraph (g) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

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

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

(3) For purposes of paragraph (g) of this section, other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer that is a member of a controlled group (as described in paragraph (e)(5) of this section), any other health insurance issuer that is a member of such controlled group;

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the rate for any plan within the product within an allowable variation of +/- 2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (g)(3)(iii) and (iv) of this section.

(h) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the individual market only through one or more associations, any reference in this section to an "individual" is deemed to include a reference to the association of which the individual is a member.

(i) *Notice of renewal of coverage.* If an issuer is renewing grandfathered coverage as described in paragraph (b) of this section, or uniformly modifying grandfathered coverage as described in paragraph (g) of this section, the issuer must provide to each individual written notice of the renewal at least 60 calendar days before the date the coverage will be

renewed in a form and manner specified by the Secretary.

§ 148.124 Certification and disclosure of coverage.

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

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

§ 148.126 Determination of an eligible individual.

The rules for guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of § 147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

§ 148.128 State flexibility in individual market reforms—alternative mechanisms.

The rules for a State to implement an acceptable alternative mechanism for purposes of guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of § 147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

SUBPART C—REQUIREMENTS RELATED TO BENEFITS

§ 148.170 Standards relating to benefits for mothers and newborns. *[Not included in this compilation.]*

§ 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 CYP2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, *W* does not pay for the tamoxifen prescription.

(ii) *Conclusion*. In this *Example 3*, *W* does not violate paragraph (e) of this section if it conditions future payments for the tamoxifen prescription on *K's* undergoing a genetic test to determine the genetic markers *K* has for making the CYP2D6 enzyme. *W* also does not violate paragraph (e) of this section if it refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *K*.

(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.

SUBPART D—PREEMPTION; EXCEPTED BENEFITS

§ 148.210 Preemption.

(a) *Scope*. (1) This section describes the effect of sections 2741 through 2763 and 2791 of the PHS Act on a State's authority to regulate health insurance issuers in the individual market. This section makes clear that States remain subject to section 514 of ERISA, which generally preempts State law that relates to ERISA-covered plans.

(2) Sections 2741 through 2763 and 2791 of the PHS Act cannot be construed to affect or modify the provisions of section 514 of ERISA.

(b) *Regulation of insurance issuers*. The individual market rules of this part do not prevent a State law from establishing, implementing, or continuing in effect standards or requirements unless the standards or requirements prevent the application of a requirement of this part.

§ 148.220 Excepted benefits.

The requirements of this part and part 147 of this subchapter do not apply to any individual coverage in relation to its provision of the benefits described in

paragraphs (a) and (b) of this section (or any combination of the benefits).

(a) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances:

(1) Coverage only for accident (including accidental death and dismemberment).

(2) Disability income insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Coverage issued as a supplement to liability insurance.

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

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

(8) Coverage for on-site medical clinics.

(9) Travel insurance, within the meaning of § 144.103 of this subchapter.

(b) *Other excepted benefits.* The requirements of this part do not apply to individual health insurance coverage described in paragraphs (b)(1) through (b)(6) of this section if the benefits are provided under a separate policy, certificate, or contract of insurance. These benefits include the following:

(1) Limited scope dental or vision benefits. These benefits are dental or vision benefits that are limited in scope to a narrow range or type of benefits that are generally excluded from benefit packages that combine hospital, medical, and surgical benefits.

(2) Long-term care benefits. These benefits are benefits that are either—

(i) Subject to State long-term care insurance laws;

(ii) For qualified long-term care insurance services, as defined in section 7702B(c)(1) of the Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Code; or

(iii) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(3) Coverage only for a specified disease or illness (for example, cancer policies) if the policies meet the requirements of § 146.145(b)(4)(ii)(B) and (C) of this subchapter regarding noncoordination of benefits. (4) Hospital indemnity or other fixed indemnity insurance only if—

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

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

(iii) The benefits are paid in a fixed dollar amount per period of hospitalization or illness and/or per service (for example, $100/day or $50/ visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage.

(iv) A notice is displayed prominently in the application materials in at least 14 point type that has the following language:

"THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE. LACK OF MAJOR MEDICAL COVERAGE (OR OTHER MINIMUM ESSENTIAL COVERAGE) MAY RESULT IN AN ADDITIONAL PAYMENT WITH YOUR TAXES."

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

(5) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act. 42 U.S.C. 1395ss, also known as Medigap or MedSupp insurance). The requirements of this part 148 (including genetic nondiscrimination requirements), do not apply to Medicare supplemental health insurance policies. However, Medicare supplemental health insurance policies are subject to similar genetic nondiscrimination requirements under section 104 of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110–233), as incorporated into the NAIC Model Regulation relating to sections 1882(s)(2)(e) and (x) of the Act (The NAIC Model Regulation can be accessed at *http://www.naic.org.*).

(6) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as CHAMPUS supplemental programs).

(7) Similar supplemental coverage provided to coverage under a group health plan (as described in § 146.145(b)(5)(i)(C) of this subchapter).

SUBPART E—GRANTS TO STATES FOR OPERATION OF QUALIFIED HIGH RISK POOLS

[*Not included in this compilation*]

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PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

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

SUBPART A—GENERAL PROVISIONS

§ 149.10 Basis and scope.

(a) *Basis.* This part implements parts D and E of title XXVII of the PHS Act.

(b) *Scope.* This part establishes standards for group health plans, health insurance issuers offering group or individual health insurance coverage, health care providers and facilities, and providers of air ambulance services with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities. This part also establishes a Patient-Provider Dispute Resolution Process and standards for certifying Selected Dispute Resolution entities.

§ 149.20 Applicability.

(a) *In general.* (1) The requirements in subparts B, D, and H of this part apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter), except as specified in paragraph (b) of this section.

(2) The requirements in subpart E of this part apply to health care providers, health care facilities, and providers of air ambulance services.

(3) The requirements in subpart F of this part apply to certified IDR entities, health care providers, health care facilities, and providers of air ambulance services and group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter) except as specified in paragraph (b) of this section.

(4) The requirements in subpart G of this part apply to Selected Dispute Resolution Entities, health care providers, providers of air ambulance services, health care facilities and uninsured (or self-pay) individuals, as defined in subpart G.

(b) *Exceptions.* The requirements in subparts B, D, E, F, and H of this part do not apply to the following:

(1) Excepted benefits as described in §§ 146.145 and 148.220 of this subchapter.

(2) Short-term, limited-duration insurance as defined in § 144.103 of this subchapter.

(3) Health reimbursement arrangements or other account-based group health plans as described in § 147.126(d) of this subchapter.

§ 149.30 Definitions.

The definitions in part 144 of this subchapter apply to this part, unless otherwise specified. In addition, for purposes of this part, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in § 149.110(c)(1).

Emergency services has the meaning given the term in § 149.110(c)(2).

Health care facility, with respect to a group health plan or group or individual health insurance

coverage, in the context of non-emergency services, is each of the following:

(1) A hospital (as defined in section 1861(e) of the Social Security Act);

(2) A hospital outpatient department;

(3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and

(4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

(1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and

(2) Provides any emergency services as described in § 149.110(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 149.110(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§ 149.110 through 149.130 are provided or covered, a written notice from the plan or issuer to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan or coverage and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in 29 CFR 2560.503–1.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan or issuer under 26 CFR 54.9816–4T(b)(3)(iv)(A), 54.9816–5T(c)(3), or 54.9817–1T(b)(4)(i); 29 CFR 2590.716–4(b)(3)(iv)(A), 2590.716–5(c)(3), or 2590.717–1(b)(4)(i); or § 149.110(b)(3)(iv)(A), § 149.120(c)(3), or § 149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan or issuer enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A–1(c) or 2799A–2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item

or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to § 149.110(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between an emergency facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between a health care facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in § 149.140(a)(13).

Service code has the meaning given the term in § 149.140(a)(14).

Qualifying payment amount has the meaning given the term in § 149.140(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with § 149.140); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage offered by a health insurance issuer to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not

otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts in to such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

SUBPART B—PROTECTIONS AGAINST BALANCE BILLING FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

§ 149.110 Preventing surprise medical bills for emergency services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan or issuer—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan or coverage and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-

day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan or coverage payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of- network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant, beneficiary, or enrollee with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in § 144.103 of this subchapter).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an independent freestanding emergency department, to

stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.* (A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(*1*) For which benefits are provided or covered under the plan or coverage; and

(*2*) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in § 149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.120 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan or issuer must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant, beneficiary, or enrollee by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of § 149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan or issuer—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan or coverage and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan or coverage payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of

this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant, beneficiary, or enrollee toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.130 Preventing surprise medical bills for air ambulance services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with § 149.140) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan or issuer must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan or coverage and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan or coverage payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–2(b)(6) of the PHS Act, or in cases where the out-of- network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.140 Methodology for calculating qualifying payment amount.

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

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in § 147.210 of this subchapter.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—

(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

(i) An emergency department of a hospital; or

(ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, the first year after 2019 for which coverage for such item or service is offered under that plan or coverage.

(6) *First sufficient information year* means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(i) In the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to

such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in § 147.126(d)(6)(i) of this subchapter, and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, but that is offered under the plan or coverage in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis- Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan or health insurance issuer offering group or individual health insurance coverage has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(18) *Downcode* means the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower qualifying payment amount than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all group or individual health insurance coverage offered by the issuer in the same insurance market for

the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan or issuer must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by such issuer that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan or issuer must—

(A) Calculate separate median contracted rates for CPT code modifiers "26" (professional component) and "TC" (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.* (i) If a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan or issuer has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount*—(1) *In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan or issuer must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI–U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the

Internal Revenue Service will calculate the percentage increase using the CPI–U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI–U for each calendar year is the average of the CPI–U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as: (CPI–U 2019/CPI–U 2018) × (CPI–U 2020/CPI–U 2019) × (CPI–U 2021/CPI–U 2020)

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI–U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI–U for each calendar year is the average of the CPI–U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as CPI– U present year/CPI–U prior year.

(iii) For anesthesia services furnished during 2022, the plan or issuer must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan or issuer must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan or issuer.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply that amount by the sum of the base unit, time unit, and

physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan or issuer must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan or issuer.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(vii) For any other items or services for which a plan or issuer generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan or issuer must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans and coverage.* With respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage in a geographic region in which the sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(i) For the first year in which the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region—

(A) If the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan or coverage and furnished during the first year; and

(B) If the plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan or issuer must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in the region, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services

furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan or issuer does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan or issuer, respectively, through use of any eligible database, and then increasing that rate by the percentage increase in the CPI–U over such preceding year. For purposes of this section, in cases in which an eligible database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan or issuer must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI– U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to 'furnished during 2022' is treated as a reference to furnished during such first sufficient information year, the reference to 'in 2019' is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to 'furnished during 2023 or a subsequent year' is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must identify a

reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan or issuer reimburses for the item or service billed under the new service code compared to the rate that the plan or issuer reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to a calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI– U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan or issuer must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With each initial payment or notice of denial of payment under § 149.110, § 149.120, or § 149.130:

(i) The qualifying payment amount for each item or service involved;

(ii) If the qualifying payment amount is based on a downcoded service code or modifier—

(A) A statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded;

(B) An explanation of why the claim was downcoded, which must include a description of which service codes were altered, if any, and a description of which modifiers were altered, added, or removed, if any; and

(C) The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded;

(iii) A statement to certify that, based on the determination of the plan or issuer—

(A) The qualifying payment amount applies for purposes of the recognized

amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iv) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(v) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for- service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code; and

(iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan or issuer that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan or issuer is responsible for any costs associated with accessing such database.

(f) *Audits.* The procedures described in part 150 of this subchapter apply with respect to ensuring that a plan or coverage is in compliance with the requirement of applying a qualifying payment amount under this subpart and ensuring that such amount so applied satisfies the requirements under this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable for plan years or in the individual market, policy years beginning on or after January 1, 2022, except that paragraph (a)(18) of this section regarding the definition of the term "downcode" and paragraph (d)(1)(ii) of this section regarding additional information that must be provided if the qualifying payment amount is based on a downcoded service code or modifier are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market, policy years beginning on or after January 1, 2022.

§ 149.150 Complaints process for surprise medical bills regarding group health plans and group and individual health insurance coverage.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process to receive and resolve complaints regarding information that a specific group health plan or health insurance issuer offering group or individual health insurance coverage may be failing to meet the requirements under this subpart, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written or oral, that indicates there has been a potential violation of the requirements under subpart B of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral or written statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. As part of the response, HHS may request additional information needed to process the complaint. Such additional information may include:

(i) Explanations of benefits;

(ii) Processed claims;

(iii) Information about the health care provider, facility, or provider of air ambulance services involved;

(iv) Information about the group health plan or health insurance issuer covering the individual;

(v) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(vi) The summary plan description, policy, certificate, contract of insurance, membership booklet, outline of coverage, or other evidence of coverage the plan or issuer provides to participants, beneficiaries, or enrollees;

(vii) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(viii) Any other information HHS may need to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint and the plan or issuer involved, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the plan or issuer;

(iii) Refer the plan or issuer for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of the resolution of the complaint and any corrective action taken.

SUBPART C—[RESERVED]

SUBPART D—ADDITIONAL PATIENT PROTECTIONS

§ 149.310 Choice of health care professional.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance

issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

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

(A) *Example 1*—(*1*) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(*2*) *Conclusion.* In this *Example 1*, the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2*—(*1*) *Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it

have an allergist participating in its network, and it therefore refuses to authorize the referral.

(*2*) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

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

(A) *Example 1*—(*1*) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(*2*) *Conclusion.* In this *Example 1*, the group health plan has violated the

requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaining gynecological services.

(B) *Example 2*—(*1*) *Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that *A* seeks gynecological services from *C*, an out-of-network provider.

(*2*) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

(C) *Example 3*—(*1*) *Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(*2*) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4*—(*1*) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(*2*) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add: For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

SUBPART E—HEALTH CARE PROVIDER, HEALTH CARE FACILITY, AND AIR AMBULANCE SERVICE PROVIDER REQUIREMENTS [Not included in this compilation]

SUBPART F—INDEPENDENT DISPUTE RESOLUTION PROCESS

§ 149.510 Independent dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group or individual health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.30 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable

health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this definition, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of reidentification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Labor and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited

duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan or coverage administrator, plan or coverage fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(ix) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(x) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xi) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or § 149.110, as applicable, for which the conditions of § 149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816– 5T, 29 CFR 2590.717–5, or § 149.120, as applicable, for which the conditions of § 149.420(c)–(i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, or § 149.130, as applicable, and for which the

out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in § 149.30;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-businessday period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(i), 29 CFR 2590.716–4(c)(2)(i), or § 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or § 149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in § 149.140(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) Manner. The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) Notice to the Secretary. The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party

in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide

information regarding Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of the Treasury and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) of this section within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, weighing only the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the

offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1*—(*1*) *Facts.* A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(A) (*Example 1*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(B) (*Example 2*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in

paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(C) (*Example 3*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4—(1) Facts.* A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(D) (*Example 4*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(E) (*Example 5*), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) The certified IDR entity's written decision must include an explanation of their determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendarday suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1) of this section, pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier.

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(*ii*) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(*iii*) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(*iv*) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(*v*) Contact procedures for individuals to ask questions or learn additional information, which must include a tollfree telephone number, email address, website, or postal address.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(v)(A) and (B) of this section, as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(*1*) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fee; and

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) Conflict-of-interest standards. In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*— (i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or

revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the Treasury, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to

those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not reapply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information.* Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after

January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraphs (c)(4)(iii)(B) through (D) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years or in the individual market policy years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021; and paragraphs (c)(4)(ii) through (iv) of this section regarding payment determinations, paragraph (c)(4)(vi)(B) of this section regarding written decisions, and paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

§ 149.520 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 149.30 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Considerations for air ambulance services.* In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Weighing considerations.* In weighing the considerations described in paragraph (b)(2) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR service, or it is already accounted for by the qualifying payment amount under § 149.510(c)(4)(iii)(A) or other credible information under § 149.510(c)(4)(iii)(B) through (D), except that the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(4) *Reporting of information relating to the IDR process.* In applying the requirements of § 149.510(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified

by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 149.510(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under § 149.510(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section and § 149.510(c)(4)(iii)(C) and (D);

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph § 149.510(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years, or in the individual market, policy years, beginning on or after January 1, 2022, except that paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(F) of this section regarding payment determinations are applicable with respect to services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

SUBPART G—PROTECTION OF UNINSURED OR SELF-PAY INDIVIDUALS [Not included in this compilation]

SUBPART H—PRESCRIPTION DRUG AND HEALTH CARE SPENDING

§ 149.710 Definitions.

For purposes of this subpart, the following definitions apply in addition to the definitions in § 149.30:

Brand prescription drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), or under section 351 of the PHS Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term "brand prescription drug" includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and that is generally marketed under a proprietary, trademark-protected name. The term "brand prescription drug" includes drugs that the U.S. Food and Drug Administration determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

Enrollee means an individual who is enrolled, within the meaning of § 144.103 of this subchapter, in group health insurance coverage, or an individual who is covered by individual health insurance coverage, at any time during the reference year, and includes dependents.

Federal Employees Health Benefits (FEHB) line of business refers to all health benefit plans that are offered to eligible enrollees pursuant to a contract between the Office of Personnel Management and Federal Employees Health Benefits (FEHB) Program carriers. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Life-years means the total number of months of coverage for participants and beneficiaries, or for enrollees, as applicable, divided by 12.

Market segment means one of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

Premium amount means, with respect to individual health insurance coverage and fully-insured group health plans, earned premium as that term is defined in § 158.130 of this subchapter, excluding the adjustments specified in § 158.130(b)(5). Premium amount means, with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on payments of premiums as defined in § 158.130 of this subchapter, the premium equivalent amount representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

Prescription drug (drug) means a set of pharmaceutical products that have been assigned a National Drug Code (NDC) by the Food and Drug Administration and are grouped by name and ingredient in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

Prescription drug rebates, fees, and other remuneration means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees.

Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Reference year means the calendar year immediately preceding the calendar year in which data submissions under this section are required.

Reporting entity means an entity that submits some or all of the information required under this subpart with respect to a plan or issuer, and that may be different from the plan or issuer that is subject to the requirements of this subpart.

Student market has the meaning given in § 158.103 of this subchapter.

Therapeutic class means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, in guidance. The Secretary may require plans and issuers to classify drugs according to a commonly available public or commercial therapeutic classification system, a therapeutic classification system provided by the Secretary, or a combination thereof.

Total annual spending means incurred claims, as that term is defined in § 158.140 of this subchapter, excluding the adjustments specified in § 158.140(b)(1)(i), (b)(2)(iv), and (b)(4), and including cost sharing. With respect to prescription drugs, total annual spending is net of prescription drug rebates, fees, and other remuneration.

§ 149.720 Reporting requirements related to prescription drug and health care spending.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit an annual report to the Secretary, the Secretary of the Treasury, and the Secretary of Labor, on prescription drug and health care spending, premiums, and enrollment under the plan or coverage.

(b) *Timing and form of report.* The report for the 2020 reference year must be submitted to the Secretary by December 27, 2021. Beginning with the 2021 reference year, the report for each reference year is due by June 1 of the year following the reference year. The report must be submitted in the form and manner prescribed by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(c) *Transfer of business.* Issuers that acquire a line or block of business from another issuer during a reference year are responsible for submitting the information and report required by this section for the acquired business for that reference year, including for the part of the reference year that was prior to the acquisition.

(d) *Reporting entities and special rules to prevent unnecessary duplication*—(1) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan may satisfy the requirements of paragraph (a) of this section if the plan requires the health insurance issuer offering the coverage to report the information required by this section in compliance with this subpart pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under paragraph (a) of this section in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the reporting requirements of paragraph (a) of this section with respect to the relevant information.

(2) *Other contractual arrangements.* A group health plan or health insurance issuer offering group or individual health insurance coverage may satisfy the requirements under paragraph (a) of this section by entering into a written agreement under which one or more other parties (such as health insurance issuers, pharmacy benefit managers, third-party administrators, or other third parties) report some or all of the information required under paragraph (a) of this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer

chooses to enter into such an agreement and the party with which it contracts fails to provide the information in accordance with paragraph (a) of this section, the plan or issuer violates the reporting requirements of paragraph (a) of this section.

(e) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 149.730 Aggregate reporting.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit, or arrange to be submitted, the information required in § 149.740(b) separately for each State in which group health coverage or group or individual health insurance coverage was provided in connection with the group health plan or by the health insurance issuer. The report must include the experience of all plans and policies in the State during the reference year covered by the report, and must include the experience separately for each market segment as defined in § 149.710.

(b) *Aggregation by reporting entity*—(1) *In general.* If a reporting entity submits data on behalf of more than one group health plan in a State and market segment, the reporting entity may aggregate the data required in § 149.740(b) for the group health plans for each market segment in the State.

(2) *Multiple reporting entities.* (i) If multiple reporting entities submit the required data related to one or more plans or issuers in a State and market segment, the data submitted by each of these reporting entities must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submits the data on total annual spending on health care services, as required by § 149.740(b)(4), on behalf of these plans or issuers.

(ii) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance alternative or additional aggregation methods for data submitted by multiple reporting entities, to ensure a balance between compliance burdens and a data aggregation level that facilitates the development of the biannual public report required under section 2799A–10(b) of the PHS Act.

(3) *Group health insurance coverage with dual contracts.* If a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, the plan's out-of-network experience may be treated as if it were all related to the contract provided by the in-network issuer.

(c) *Aggregation by State.* (1) Experience with respect to each fully-insured policy must be included on the report for the State where the contract was issued, except as specified in paragraphs (c)(3) and (4) of this section.

(2) Experience with respect to each self-funded group health plan must be included on the report for the State where the plan sponsor has its principal place of business.

(3) For individual market business sold through an association, experience must be attributed to the issue State of the certificate of coverage.

(4) For health coverage provided to plans through a group trust or multiple employer welfare arrangement, the experience must be included in the report for the State where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an employer under ERISA section 3(5)) has its principal place of business or the State where the association is incorporated, in the case of an association with no principal place of business.

(d) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 149.740 Required information.

(a) *Information for each plan or coverage.* The report required under § 149.720 must include the following information for each plan or coverage, at the plan or coverage level:

(1) The identifying information for plans, issuers, plan sponsors, and any other reporting entities.

(2) The beginning and end dates of the plan year that ended on or before the last day of the reference year.

(3) The number of participants, beneficiaries, and enrollees, as applicable, covered on the last day of the reference year.

(4) Each State in which the plan or coverage is offered.

(b) *Information for each state and market segment.* The report required under § 149.720 must include the following information with respect to plans or coverage for each State and market segment for the reference year, unless otherwise specified:

(1) The 50 brand prescription drugs most frequently dispensed by pharmacies, and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most frequently dispensed drugs must be determined according to total number of paid claims for prescriptions filled during the reference year for each drug.

(2) The 50 most costly prescription drugs and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most costly drugs must be determined according to total annual spending on each drug.

(3) The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year, and for each such drug: The data elements listed in paragraph (b)(5) of this section for the year immediately preceding the reference year, and the data elements listed in paragraph (b)(5) of this section for the reference year. The drugs with the greatest increase in expenditures must be determined based on the increase in total annual spending from the year immediately preceding the reference year to the reference year. A drug must be approved for marketing or issued an Emergency Use Authorization by the Food and Drug Administration for the entirety of the year immediately preceding the reference year and for the entirety of the reference year to be included in the data submission as one of the drugs with the greatest increase in expenditures.

(4) Total annual spending on health care services by the plan or coverage and by participants, beneficiaries, and enrollees, as applicable, broken down by the type of costs, including—

(i) Hospital costs;

(ii) Health care provider and clinical service costs, for primary care and specialty care separately;

(iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and

(iv) Other medical costs, including wellness services.

(5) Prescription drug spending and utilization, including—

(i) Total annual spending by the plan or coverage;

(ii) Total annual spending by the participants, beneficiaries, and enrollees, as applicable, enrolled in the plan or coverage, as applicable;

(iii) The number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim;

(iv) Total dosage units dispensed; and

(v) The number of paid claims.

(6) Premium amounts, including—

(i) Average monthly premium amount paid by employers and other plan sponsors on behalf of participants, beneficiaries, and enrollees, as applicable;

(ii) Average monthly premium amount paid by participants, beneficiaries, and enrollees, as applicable; and

(iii) Total annual premium amount and the total number of life-years.

(7) Prescription drug rebates, fees, and other remuneration, including—

(i) Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

(ii) Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants, beneficiaries, and enrollees, as applicable, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer; and the data elements listed in paragraph (b)(5) of this section—

(A) For each therapeutic class; and

(B) For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year.

(8) The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable.

(9) The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts.

(c) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS [Not included in this compilation]

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM [Not included in this compilation]

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT [Not included in this compilation]