

§ 146.180, Nt.

State from making an election under this section.

[79 FR 30336, May 27, 2014]

EFFECTIVE DATE NOTE: At 89 FR 77751, Sept. 23, 2024, §146.180 was amended, effective Nov. 22, 2024, by:

1. Revising paragraph (a)(2);
2. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8);
3. Adding new paragraph (a)(3);
4. Revising newly redesignated paragraphs (a)(5) and (a)(7)(i) and paragraph (f)(1); and
5. Adding paragraph (f)(4)(iii).

For the convenience of the user, the added and revised text is set forth as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) * * *

(2) *General rule.* For plans years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not provided through health insurance coverage (that is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, except as provided in paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(3) *Sunset of election option related to parity in mental health and substance use disorder benefits.* A sponsor of a non-Federal governmental plan may not newly elect to exempt its plans from the requirements described in paragraph (a)(1)(v) of this section on or after December 29, 2022.

* * * * *

(5) *Examples—(i) Example 1.* A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1st of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(ii) *Example 2.* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to 5 plan years, October 1, 2009, through September 30, 2014. For the plan year that begins on October 1,

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2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraphs (a)(1)(i) through (iii) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

* * * * *

(7) * * *

(i) Subject to paragraph (a)(7)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

* * * * *

(f) * * *

(1) *Election renewal.* A plan sponsor may renew an election under this section through subsequent elections. Notwithstanding the previous sentence and except as provided in paragraph (f)(4)(iii) of this section, an election with respect to the requirements described in paragraph (a)(1)(v) of this section expiring on or after June 27, 2023, may not be renewed. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

* * * * *

(4) * * *

(iii) In the case of a plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to the requirements described in paragraph (a)(1)(v) of this section in effect as of December 29, 2022, that expires on or after June 27, 2023, the plan may extend such election until the date on which the term of the last such agreement expires.

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

Sec.

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AUTHORITY: 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92, and 300gg-111 through 300gg-139, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

SOURCE: 75 FR 27138, May 13, 2010, unless otherwise noted.

§ 147.100 Basis and scope.

Part 147 of this subchapter implements the requirements of the Patient Protection and Affordable Care Act that apply to group health plans and health insurance issuers in the Group and Individual markets.

§ 147.102 Fair health insurance premiums.

(a) *In general.* With respect to the premium rate charged by a health insurance issuer in accordance with § 156.80 of this subchapter for health insurance coverage offered in the individual or small group market—

(1) The rate may vary with respect to the particular plan or coverage involved only by determining the following:

(i) Whether the plan or coverage covers an individual or family.

(ii) Rating area, as established in accordance with paragraph (b) of this section. For purposes of this paragraph (a), rating area is determined—

(A) In the individual market, using the primary policyholder's address.

(B) In the small group market, using the group policyholder's principal business address. For purposes of this paragraph (a)(1)(ii)(B), principal business address means the principal business address registered with the State or, if a principal business address is not registered with the State, or is registered solely for purposes of service of process and is not a substantial worksite for the policyholder's business, the business address within the State where the greatest number of employees of such policyholder works. If, for a network plan, the group policyholder's principal business address is not within the service area of such plan, and the policyholder has employees who live, reside, or work within the service area, the principal business address for purposes of the network plan is the business address within the plan's service area where the greatest number of employees work as of the beginning of the plan year. If there is no such business address, the rating area for purposes of the network plan is the rating area that reflects where the greatest number of employees within the plan's service area live or reside as of the beginning of the plan year.

(iii) Age, except that the rate may not vary by more than 3:1 for like individuals of different age who are age 21 and older and that the variation in rate must be actuarially justified for individuals under age 21, consistent with the uniform age rating curve under paragraph (e) of this section. For purposes of identifying the appropriate age adjustment under this paragraph and the age band under paragraph (d) of this section applicable to a specific enrollee, the enrollee's age as of the date of policy issuance or renewal must be used.

(iv) Subject to section 2705 of the Public Health Service Act and its implementing regulations (related to prohibiting discrimination based on health status and programs of health promotion or disease prevention) as applicable, tobacco use, except that such rate may not vary by more than 1.5:1 and may only be applied with respect to individuals who may legally use tobacco under federal and state law. For purposes of this section, tobacco use means use of tobacco on average four or more times per week within no longer than the past 6 months. This includes all tobacco products, except that tobacco use does not include religious or ceremonial use of tobacco. Further, tobacco use must be defined in terms of when a tobacco product was last used.

(2) The rate must not vary with respect to the particular plan or coverage involved by any other factor not described in paragraph (a)(1) of this section.

(b) *Rating area.* (1) A state may establish one or more rating areas within that state, as provided in paragraphs (b)(3) and (b)(4) of this section, for purposes of applying this section and the requirements of title XXVII the Public Health Service Act and title I of the Patient Protection and Affordable Care Act.

(2) If a state does not establish rating areas as provided in paragraphs (b)(3) and (b)(4) of this section or provide information on such rating areas in accordance with §147.103, or CMS determines in accordance with paragraph (b)(5) of this section that a state's rating areas under paragraph (b)(4) of this section are not adequate, the default will be one rating area for each metropolitan statistical area in the state and one rating area comprising all non-metropolitan statistical areas in the state, as defined by the Office of Management and Budget.

(3) A state's rating areas must be based on the following geographic boundaries: Counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas, as defined by the Office of Management and Budget, and will be presumed adequate if either of the following conditions are satisfied:

(i) The state established by law, rule, regulation, bulletin, or other executive action uniform rating areas for the entire state as of January 1, 2013.

(ii) The state establishes by law, rule, regulation, bulletin, or other executive action after January 1, 2013 uniform rating areas for the entire state that are no greater in number than the number of metropolitan statistical areas in the state plus one.

(4) Notwithstanding paragraph (b)(3) of this section, a state may propose to CMS for approval a number of rating areas that is greater than the number described in paragraph (b)(3)(ii) of this section, provided such rating areas are based on the geographic boundaries specified in paragraph (b)(3) of this section.

(5) In determining whether the rating areas established by each state under paragraph (b)(4) of this section are adequate, CMS will consider whether the state's rating areas are actuarially justified, are not unfairly discriminatory, reflect significant differences in health care unit costs, lead to stability in rates over time, apply uniformly to all issuers in a market, and are based on the geographic boundaries of counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas.

(c) *Application of variations based on age or tobacco use.* With respect to family coverage under health insurance coverage, the rating variations permitted under paragraphs (a)(1)(iii) and (a)(1)(iv) of this section must be applied based on the portion of the premium attributable to each family member covered under the coverage.

(1) *Per-member rating.* The total premium for family coverage must be determined by summing the premiums for each individual family member. With respect to family members under the age of 21, the premiums for no more than the three oldest covered children must be taken into account in determining the total family premium.

(2) *Family tiers under community rating.* If a state does not permit any rating variation for the factors described in paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the state may require that premiums for family coverage be determined by using uniform family tiers

and the corresponding multipliers established by the state. If a state does not establish uniform family tiers and the corresponding multipliers, the per-member-rating methodology under paragraph (c)(1) of this section will apply in that state.

(3) *Application to small group market—*

(i) In the case of the small group market, the total premium charged to a group health plan is determined by summing the premiums of covered participants and beneficiaries in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(ii) Subject to paragraph (c)(3)(iii) of this section, nothing in this section prevents a state from requiring issuers to offer to a group health plan, or an issuer from voluntarily offering to a group health plan, premiums that are based on average enrollee premium amounts, provided that the total group premium established at the time of applicable enrollment at the beginning of the plan year is the same total amount derived in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(iii) Effective for plan years beginning on or after January 1, 2015, an issuer that, in connection with a group health plan in the small group market, offers premiums that are based on average enrollee premium amounts under paragraph (c)(3)(ii) of this section must—

(A) Ensure an average enrollee premium amount calculated based on applicable enrollment of participants and beneficiaries at the beginning of the plan year does not vary during the plan year.

(B) Unless a state establishes and CMS approves an alternate rating methodology, calculate an average enrollee premium amount for covered individuals age 21 and older, and calculate an average enrollee premium amount for covered individuals under age 21. The premium for a given family composition is determined by summing the average enrollee premium amount applicable to each family member covered under the plan, taking into account no more than three covered children under age 21.

(C) Pursuant to applicable state law, ensure that the average enrollee pre-

mium 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

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group market in the state to offer such coverage through an Exchange starting in 2017, the provisions of this section applicable to coverage in the small group market apply to all coverage offered in the large group market in the state.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

[78 FR 13436, Feb. 27, 2013, as amended at 78 FR 54133, Aug. 30, 2013; 79 FR 13834, Mar. 11, 2014; 81 FR 12334, Mar. 8, 2016; 81 FR 94173, Dec. 22, 2016; 83 FR 17058, Apr. 17, 2018]

§ 147.103 State reporting.

(a) *2014.* If a state has adopted or intends to adopt for the 2014 plan or policy year a standard or requirement described in this paragraph, the state must submit to CMS information about such standard or requirement in a form and manner specified in guidance by the Secretary no later than March 29, 2013. A state standard or requirement is described in this paragraph if it includes any of the following:

(1) A ratio narrower than 3:1 in connection with establishing rates for individuals who are age 21 and older, pursuant to § 147.102(a)(1)(iii).

(2) A ratio narrower than 1.5:1 in connection with establishing rates for individuals who use tobacco legally, pursuant to § 147.102(a)(1)(iv).

(3) Geographic rating areas, pursuant to § 147.102(b).

(4) In states that do not permit rating based on age or tobacco use, uniform family tiers and corresponding multipliers, pursuant to § 147.102(c)(2).

(5) A requirement that 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

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2014 plan or policy year), the state must submit to CMS information about such standard in a form and manner specified in guidance by the Secretary.

(c) *Applicability date.* The provisions of this section apply on March 29, 2013.

[78 FR 13437, Feb. 27, 2013]

§ 147.104 Guaranteed availability of coverage.

(a) *Guaranteed availability of coverage in the individual and group market.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer that offers health insurance coverage in the individual, small group, or large group market in a State must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.

(b) *Enrollment periods.* A health insurance issuer may restrict enrollment in health insurance coverage to open or special enrollment periods.

(1) *Open enrollment periods*—(i) *Group market.* (A) Subject to paragraph (b)(1)(i)(B) of this section, a health insurance issuer in the group market must allow an employer to purchase health insurance coverage for a group health plan at any point during the year.

(B) In the case of a group health plan in the small group market that cannot comply with employer contribution or group participation rules for the offering of health insurance coverage, as allowed under applicable State law, and in the case of a QHP offered in the SHOP, as permitted by § 156.285(e) or § 156.286(e) of this subchapter, a health insurance issuer may restrict the availability of coverage to an annual enrollment period that begins November 15 and extends through December 15 of each calendar year.

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a SHOP in a State, for a group enrollment received on the first through the fifteenth day of any month, the coverage effective date must be no later than the first day of the following month. For a group enrollment received on the 16th through

last day of any month, the coverage effective date must be no later than the first day of the second following month. In either such case, a small employer may instead opt for a later effective date within a quarter for which small group market rates are available.

(ii) *Individual market.* A health insurance issuer in the individual market must allow an individual to purchase health insurance coverage during the initial and annual open enrollment periods described in § 155.410(b) and (e) of this subchapter. Coverage must become effective consistent with the dates described in § 155.410(c) and (f) of this subchapter.

(2) *Limited open enrollment periods.* (i) A health insurance issuer in the individual market must provide a limited open enrollment period for the triggering events described in § 155.420(d) of this subchapter, excluding, with respect to coverage offered outside of an Exchange, the following:

(A) Section 155.420(d)(3) of this subchapter (concerning Exchange eligibility standards);

(B) Section 155.420(d)(6) of this subchapter (to the extent concerning eligibility for advance payments of the premium tax credit or change in eligibility for cost-sharing reductions other than ineligibility);

(C) Section 155.420(d)(8) of this subchapter (concerning Indians);

(D) Section 155.420(d)(9) of this subchapter (concerning exceptional circumstances);

(E) Section 155.420(d)(12) of this subchapter (concerning plan and benefit display errors);

(F) Section 155.420(d)(13) of this subchapter (concerning eligibility for insurance affordability programs or enrollment in the Exchange); and

(G) Section 155.420(d)(16) of this subchapter (concerning eligibility for advance payments of the premium tax credit and household income, as defined in 26 CFR 1.36B-1(e), that is expected to be no greater than 150 percent of the Federal poverty level).

(ii) In applying this paragraph (b)(2), a reference in § 155.420 (other than in § 155.420(a)(5) and (d)(4)) of this subchapter to a “QHP” is deemed to refer to a plan, a reference to “the Ex-

change” 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 indi-

viduals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to any employer or individual in a state under paragraph (d)(1) of this section may not offer coverage in the large group, small group, or individual market, as applicable, in the State before the later of either of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable state authority, if required under applicable state law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable state authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), expected length of life, degree of medical dependency, quality of life, or other health conditions.

(f) *Calendar year plans.* An issuer that offers coverage in the individual market, or in a merged market in a State

that has elected to merge the individual market and small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, must ensure that such coverage is offered on a calendar year basis with a policy year ending on December 31 of each calendar year.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

(i) *Coverage denials for failure to pay premiums for prior coverage.* A health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates paragraph (a) of this section.

(j) *Construction.* Nothing in this section should be construed to require an issuer to offer coverage otherwise prohibited under applicable Federal law.

[78 FR 13437, Feb. 27, 2013, as amended at 78 FR 65092, Oct. 30, 2013; 78 FR 76217, Dec. 17, 2013; 79 FR 30339, May 27, 2014; 79 FR 59138, Oct. 1, 2014; 80 FR 10862, Feb. 27, 2015; 81 FR 94173, Dec. 22, 2016; 82 FR 18381, Apr. 18, 2017; 83 FR 17058, Apr. 17, 2018; 85 FR 37247, June 19, 2020; 86 FR 24285, May 5, 2021; 86 FR 53503, Sept. 27, 2021; 87 FR 27386, May 6, 2022; 89 FR 37703, May 6, 2024]

§ 147.106 Guaranteed renewability of coverage.

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

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

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

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

(3) *Violation of participation or contribution rules.* In the case of group health insurance coverage, the plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, pursuant to applicable state law. For purposes of this paragraph the following apply:

(i) The term “employer contribution rule” means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries.

(ii) The term “group participation rule” means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

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

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 147.104(c)(1)(i); provided the issuer provides notice in accordance with the requirements of paragraph (c)(1) of this section.

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the bona fide association ceases, but only if the

coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

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

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

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

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or individuals, as applicable, or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* (1) An issuer may elect to discontinue offering all health insurance coverage in the individual, small group, or large group market, or all markets, in a State in accordance with applicable State law only if—

(i) The issuer provides notice in writing to the applicable state authority and to each plan sponsor or individual, as applicable, (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 calendar days prior to the date the coverage will be discontinued; and

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

(2) An issuer that elects to discontinue offering all health insurance coverage in a market (or markets) in a state as described in this paragraph (d) may not issue coverage in the applicable market (or markets) and state involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

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

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

(ii) The issuer—

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

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

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products

for purposes of the process and requirements applied pursuant to paragraph (d)(3)(ii)(B) of this section.

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

(e) *Exception for uniform modification of coverage.* (1) Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan or an individual, as applicable, in the following:

(i) Large group market.

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

(iii) Individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

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

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

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

(3) Other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product in the individual or small group market meets all of the following criteria:

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

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

ple, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

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

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the 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

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must notify HHS in a manner specified by HHS, by the latest of—

(1) The date the transaction is entered into; or

(2) The 30th day prior to the effective date of the transaction.

(h) *Construction.* (1) Nothing in this section should be construed to require an issuer to renew or continue in force coverage for which continued eligibility would otherwise be prohibited under applicable Federal law.

(2) Medicare entitlement or enrollment is not a basis to nonrenew an individual's health insurance coverage in the individual market under the same policy or contract of insurance.

(i) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to “plan sponsor” is deemed, with respect to coverage provided to an employer member of the association, to include a reference to the employer.

(j) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(k) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

[78 FR 13437, Feb. 27, 2013, as amended at 78 FR 65092, Oct. 30, 2013; 79 FR 30339, May 27, 2014; 79 FR 42985, July 24, 2014; 79 FR 53004, Sept. 5, 2014; 80 FR 10862, Feb. 27, 2015; 81 FR 94173, Dec. 22, 2016; 84 FR 17561, Apr. 25, 2019]

§ 147.108 Prohibition of preexisting condition exclusions.

(a) *In general.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103 of this subchapter).

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

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expi-

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ration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1*, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. Therefore, such an exclusion is prohibited.

Example 2. (i) *Facts.* Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) *Conclusion.* See *Example 2* in § 146.111(a)(2) of this subchapter for a conclusion that M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(c) *Allowable screenings to determine eligibility for alternative coverage in the individual market—*(1) *In general.* (i) A health insurance issuer offering individual health insurance coverage may screen applicants for eligibility for alternative coverage options before offering a child-only policy if—

(A) The practice is permitted under State law;

(B) The screening applies to all child-only applicants, regardless of health status; and

(C) The alternative coverage options include options for which healthy children would potentially be eligible (*e.g.*, Children's Health Insurance Program (CHIP) or group health insurance).

(ii) An issuer must provide such coverage to an applicant effective on the first date that a child-only policy would have been effective had the applicant not been screened for an alternative coverage option, as provided by State law. A State may impose a reasonable time limit by when an issuer would have to enroll a child regardless of pending applications for other coverage.

(2) *Restrictions.* A health insurance issuer offering individual health insurance coverage may screen applicants

for eligibility for alternative coverage provided that:

(i) The screening process does not by its operation significantly delay enrollment or artificially engineer eligibility of a child for a program targeted to individuals with a pre-existing condition;

(ii) The screening process is not applied to offers of dependent coverage for children; or

(ii) The issuer does not consider whether an applicant is eligible for, or is provided medical assistance under, Medicaid in making enrollment decisions, as provided under 42 U.S.C. 1396a (25)(G).

(d) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

[80 FR 72274, Nov. 18, 2015]

EDITORIAL NOTE: At 80 FR 72284, Nov. 18, 2015, § 147.108 was revised to include two paragraphs (c)(2)(ii).

§ 147.110 Prohibiting discrimination against participants, beneficiaries, and individuals based on a health factor.

(a) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must comply with all the requirements under 45 CFR 146.121 applicable to a group health plan and a health insurance issuer offering group health insurance coverage. Accordingly, with respect to an issuer offering health insurance coverage in the individual market, the issuer is subject to the requirements of § 146.121 to the same extent as an issuer offering group health insurance coverage, except the exception contained in § 146.121(f) (concerning nondiscriminatory wellness programs) does not apply.

(b) *Applicability date.* This section is applicable to group health plans and health insurance issuers offering group or individual health insurance coverage for plan years (in the individual

market, policy years) beginning on or after January 1, 2014. See § 147.140, which provides that the rules of this section do not apply to grandfathered health plans that are individual health insurance coverage.

[78 FR 33192, June 3, 2013]

§ 147.116 Prohibition on waiting periods that exceed 90 days.

(a) *General rule.* A group health plan, and a health insurance issuer offering group health insurance coverage, must not apply any waiting period that exceeds 90 days, in accordance with the rules of this section. If, under the terms of a plan, an individual can elect coverage that would begin on a date that is not later than the end of the 90-day waiting period, this paragraph (a) is considered satisfied. Accordingly, in that case, a plan or issuer will not be considered to have violated this paragraph (a) solely because individuals take, or are permitted to take, additional time (beyond the end of the 90-day waiting period) to elect coverage.

(b) *Waiting period defined.* For purposes of this part, a waiting period is the period that must pass before coverage for an individual who is otherwise eligible to enroll under the terms of a group health plan can become effective. If an individual enrolls as a late enrollee (as defined under § 144.103 of this subchapter) or special enrollee (as described in § 146.117 of this subchapter), any period before such late or special enrollment is not a waiting period.

(c) *Relation to a plan's eligibility criteria*—(1) *In general.* Except as provided in paragraphs (c)(2) and (c)(3) of this section, being otherwise eligible to enroll under the terms of a group health plan means having met the plan's substantive eligibility conditions (such as, for example, being in an eligible job classification, achieving job-related licensure requirements specified in the plan's terms, or satisfying a reasonable and bona fide employment-based orientation period). Moreover, except as provided in paragraphs (c)(2) and (c)(3) of this section, nothing in this section requires a plan sponsor to offer coverage to any particular individual or class of individuals (including, for example, part-time employees). Instead,

this section prohibits requiring otherwise eligible individuals to wait more than 90 days before coverage is effective. *See also* section 4980H of the Code and its implementing regulations for an applicable large employer's shared responsibility to provide health coverage to full-time employees.

(2) *Eligibility conditions based solely on the lapse of time.* Eligibility conditions that are based solely on the lapse of a time period are permissible for no more than 90 days.

(3) *Other conditions for eligibility.* Other conditions for eligibility under the terms of a group health plan are generally permissible under PHS Act section 2708, unless the condition is designed to avoid compliance with the 90-day waiting period limitation, determined in accordance with the rules of this paragraph (c)(3).

(i) *Application to variable-hour employees in cases in which a specified number of hours of service per period is a plan eligibility condition.* If a group health plan conditions eligibility on an employee regularly having a specified number of hours of service per period (or working full-time), and it cannot be determined that a newly-hired employee is reasonably expected to regularly work that number of hours per period (or work full-time), the plan may take a reasonable period of time, not to exceed 12 months and beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date, to determine whether the employee meets the plan's eligibility condition. Except in cases in which a waiting period that exceeds 90 days is imposed in addition to a measurement period, the time period for determining whether such an employee meets the plan's eligibility condition will not be considered to be designed to avoid compliance with the 90-day waiting period limitation if coverage is made effective no later than 13 months from the employee's start date plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month.

(ii) *Cumulative service requirements.* If a group health plan or health insurance issuer conditions eligibility on an em-

ployee'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 pe-

riod. *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 con-

sidered to be designed to avoid compliance with the 90-day waiting period limitation. Accordingly, plan coverage for *H* must begin no later than February 14, which is the 91st day after *H* completes the orientation period. (If the orientation period was longer than one month, it would be considered to be a subterfuge for the passage of time and designed to avoid compliance with the 90-day waiting period limitation. Accordingly it would violate the rules of this section.)

(g) *Special rule for health insurance issuers.* To the extent coverage under a group health plan is insured by a health insurance issuer, the issuer is permitted to rely on the eligibility information reported to it by the employer (or other plan sponsor) and will not be considered to violate the requirements of this section with respect to its administration of any waiting period, if both of the following conditions are satisfied:

(1) The issuer requires the plan sponsor to make a representation regarding the terms of any eligibility conditions or waiting periods imposed by the plan sponsor before an individual is eligible to become covered under the terms of the plan (and requires the plan sponsor to update this representation with any changes), and

(2) The issuer has no specific knowledge of the imposition of a waiting period that would exceed the permitted 90-day period.

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of State or Federal law (including ERISA, the Code, or other provisions of the Patient Protection and Affordable Care Act). See e.g., §146.121 of this subchapter and §147.110, which prohibits discrimination in eligibility for coverage based on a health factor and Code section 4980H, which generally requires applicable large employers to offer coverage to full-time employees and their dependents or make an assessable payment.

(i) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2015. See §147.140 providing that the prohibition on waiting periods exceeding 90 days applies to all group health plans and

group health insurance issuers, including grandfathered health plans.

[79 FR 10315, Feb. 24, 2014, as amended at 79 FR 35948, June 25, 2014]

§ 147.120 Eligibility of children until at least age 26.

(a) *In general.* (1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example*, the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent—(1) In general.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict dependent coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or primary subscriber, or any other person); residency with the participant (in the individual market, the primary subscriber) or with any other person; whether the child lives, works, or resides in an HMO's service area or other network service area; marital status; student status; employment; eligibility for other coverage; or any combination of those factors. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may require coverage of certain children.)

(2) *Construction.* A plan or issuer will not fail to satisfy the requirements of this section if the plan or issuer limits

dependent child coverage to children under age 26 who are described in section 152(f)(1) of the Code. For an individual not described in Code section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for dependent child health coverage, such as a condition that the individual be a dependent for income tax purposes.

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

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

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1*, the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3*, the plan violates the requirement of paragraph (d) of this section because the plan, by limiting

children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

Example 4. (i) *Facts.* A group health plan sponsored by a large employer normally charges a copayment for physician visits that do not constitute preventive services. The plan charges this copayment to individuals age 19 and over, including employees, spouses, and dependent children, but waives it for those under age 19.

(ii) *Conclusion.* In this *Example 4*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. While the requirement of paragraph (d) of this section generally prohibits distinctions based upon age in dependent coverage of children, it does not prohibit distinctions based upon age that apply to all coverage under the plan, including coverage for employees and spouses as well as dependent children. In this *Example 4*, the copayments charged to dependent children are the same as those charged to employees and spouses. Accordingly, the arrangement described in this *Example 4* (including waiver, for individuals under age 19, of the generally applicable copayment) does not violate the requirement of paragraph (d) of this section.

(f) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

[80 FR 72275, Nov. 18, 2015]

§ 147.126 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii) and (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of

essential health benefits for any individual, whether provided in-network or out-of-network.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) offered through a cafeteria plan pursuant to section 125 of the Internal Revenue Code is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term “essential health benefits” means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations. For the purpose of this section, a group health plan or a health insurance issuer that is not required to provide essential health benefits under section 1302(b) must define “essential health benefits” in a manner that is consistent with the following:

(1) For plan years beginning before January 1, 2020, one of the EHB-benchmark plans applicable in a State under §156.110 of this subchapter, and including coverage of any additional required benefits that are considered essential health benefits consistent with §155.170(a)(2) of this subchapter, or one

of the three Federal Employees Health Benefits Program (FEHBP) plan options as defined by § 156.100(a)(3) of this subchapter, supplemented as necessary, to satisfy the standards in § 156.110 of this subchapter; or

(2) For plan years beginning on or after January 1, 2020, an EHB-benchmark plan selected by a State in accordance with the available options and requirements for EHB-benchmark plan selection at § 156.111 of this subchapter, including an EHB-benchmark plan in a State that takes no action to change its EHB-benchmark plan and thus retains the EHB-benchmark plan applicable in that State for the prior year in accordance with § 156.111(d)(1) of this subchapter, and including coverage of any additional required benefits that are considered essential health benefits consistent with § 155.170(a)(2) of this subchapter.

(d) *Health reimbursement arrangements (HRAs) and other account-based group health plans*—(1) *In general.* If an HRA or other account-based group health plan is integrated with another group health plan or individual health insurance coverage and the other group health plan or individual health insurance coverage, as applicable, separately is subject to and satisfies the requirements in PHS Act section 2711 and paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based group health plan are limited does not cause the HRA or other account-based group health plan to fail to satisfy the requirements of PHS Act section 2711 and paragraph (a)(2) of this section. Similarly, if an HRA or other account-based group health plan is integrated with another group health plan or individual health insurance coverage and the other group health plan or individual health insurance coverage, as applicable, separately is subject to and satisfies the requirements in PHS Act section 2713 and § 147.130(a)(1) of this subchapter, the fact that the benefits under the HRA or other account-based group health plan are limited does not cause the HRA or other account-based group health plan to fail to satisfy the requirements of PHS Act section 2713 and § 147.130(a)(1) of this subchapter. For the purpose of this paragraph (d), all individual health

insurance coverage, except for coverage that consists solely of excepted benefits, is treated as being subject to and complying with PHS Act sections 2711 and 2713.

(2) *Requirements for an HRA or other account-based group health plan to be integrated with another group health plan.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of PHS Act section 2711 and paragraph (a)(2) of this section if it satisfies the requirements under one of the integration methods set forth in paragraph (d)(2)(i) or (ii) of this section. For purposes of the integration methods under which an HRA or other account-based group health plan is integrated with another group health plan, integration does not require that the HRA or other account-based group health plan and the other group health plan with which it is integrated share the same plan sponsor, the same plan document or governing instruments, or file a single Form 5500, if applicable. An HRA or other account-based group health plan integrated with another group health plan for purposes of PHS Act section 2711 and paragraph (a)(2) of this section may not be used to purchase individual health insurance coverage unless that coverage consists solely of excepted benefits, as defined in § 148.220 of this subchapter.

(i) *Method for integration with a group health plan: Minimum value not required.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of this paragraph (d) if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan) to the employee that does not consist solely of excepted benefits;

(B) The employee receiving the HRA or other account-based group health plan is actually enrolled in a group health plan (other than the HRA or other account-based group health plan) that does not consist solely of excepted benefits, regardless of whether the plan is offered by the same plan sponsor (referred to as non-HRA group coverage);

(C) The HRA or other account-based group health plan is available only to employees who are enrolled in non-

HRA group coverage, regardless of whether the non-HRA group coverage is offered by the plan sponsor of the HRA or other account-based group health plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA group coverage, such as a group health plan maintained by the employer of the employee's spouse);

(D) The benefits under the HRA or other account-based group health plan are limited to reimbursement of one or more of the following—co-payments, co-insurance, deductibles, and premiums under the non-HRA group coverage, as well as medical care expenses that do not constitute essential health benefits as defined in paragraph (c) of this section; and

(E) Under the terms of the HRA or other account-based group health plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based group health plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan (see paragraph (d)(3) of this section for additional rules regarding forfeiture and waiver).

(ii) *Method for integration with another group health plan: Minimum value required.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of this paragraph (d) if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan) to the employee that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Code (and its implementing regulations and applicable guidance);

(B) The employee receiving the HRA or other account-based group health plan is actually enrolled in a group health plan (other than the HRA or other account-based group health plan) that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Code

(and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based group health plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based group health plan is available only to employees who are actually enrolled in non-HRA MV group coverage, regardless of whether the non-HRA MV group coverage is offered by the plan sponsor of the HRA or other account-based group health plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA MV group coverage, such as a group health plan maintained by an employer of the employee's spouse); and

(D) Under the terms of the HRA or other account-based group health plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based group health plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan (see paragraph (d)(3) of this section for additional rules regarding forfeiture and waiver).

(3) *Forfeiture.* For purposes of integration under paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section, forfeiture or waiver occurs even if the forfeited or waived amounts may be reinstated upon a fixed date, a participant's death, or the earlier of the two events (the reinstatement event). For the purpose of this paragraph (d)(3), coverage under an HRA or other account-based group health plan is considered forfeited or waived prior to a reinstatement event only if the participant's election to forfeit or waive is irrevocable, meaning that, beginning on the effective date of the election and through the date of the reinstatement event, the participant and the participant's beneficiaries have no access to amounts credited to the HRA or other account-based group health plan. This

means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based group health plan may not be used to reimburse or pay medical care expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *Requirements for an HRA or other account-based group health plan to be integrated with individual health insurance coverage or Medicare Part A and B or Medicare Part C.* An HRA or other account-based group health plan is integrated with individual health insurance coverage or Medicare Part A and B or Medicare Part C (and treated as complying with PHS Act sections 2711 and 2713) if the HRA or other account-based group health plan satisfies the requirements of § 146.123(c) of this subchapter (as modified by § 146.123(e), for HRAs or other account-based group health plans integrated with Medicare Part A and B or Medicare Part C).

(5) *Integration with Medicare Part B and D.* For employers that are not required to offer their non-HRA group health plan coverage to employees who are Medicare beneficiaries, an HRA or other account-based group health plan that may be used to reimburse premiums under Medicare Part B or D may be integrated with Medicare (and deemed to comply with PHS Act sections 2711 and 2713) if the following requirements are satisfied with respect to employees who would be eligible for the employer's non-HRA group health plan but for their eligibility for Medicare (and the integration rules under paragraphs (d)(2)(i) and (ii) of this section continue to apply to employees who are not eligible for Medicare):

(i) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan and that does not consist solely of excepted benefits) to employees who are not eligible for Medicare;

(ii) The employee receiving the HRA or other account-based group health plan is actually enrolled in Medicare Part B or D;

(iii) The HRA or other account-based group health plan is available only to employees who are enrolled in Medicare Part B or D; and

(iv) The HRA or other account-based group health plan complies with para-

graphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Definitions.* The following definitions apply for purposes of this section.

(i) *Account-based group health plan.* An account-based group health plan is an employer-provided group health plan that provides reimbursements of medical care expenses with the reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based group health plan. An account-based group health plan does not include a qualified small employer health reimbursement arrangement, as defined in section 9831(d)(2) of the Code.

(ii) *Medical care expenses.* Medical care expenses means expenses for medical care as defined under section 213(d) of the Code.

(e) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2020. Until the applicability date for this section, plans and issuers are required to continue to comply with the corresponding sections of this subchapter B, contained in the 45 CFR, subtitle A, parts 1–199, revised as of October 1, 2018.

[80 FR 72276, Nov. 18, 2015, as amended at 81 FR 75326, Oct. 31, 2016; 84 FR 29025, June 20, 2019]

§ 147.128 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30

days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if —

(i) The cancellation or discontinuance of coverage has only a prospective effect;

(ii) The cancellation or discontinuance of coverage is effective retroactively, to the extent it is attributable to a failure to timely pay required premiums or contributions (including COBRA premiums) towards the cost of coverage;

(iii) The cancellation or discontinuance of coverage is initiated by the individual (or by the individual's authorized representative) and the sponsor, employer, plan, or issuer does not, directly or indirectly, take action to influence the individual's decision to cancel or discontinue coverage retroactively or otherwise take any adverse action or retaliate against, interfere with, coerce, intimidate, or threaten the individual; or

(iv) The cancellation or discontinuance of coverage is initiated by the Exchange pursuant to § 155.430 of this subchapter (other than under paragraph (b)(2)(iii) of this section).

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

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an inten-

tional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146 of this subchapter. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A*'s visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1*, the plan cannot rescind *A*'s coverage because *A*'s failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B*. After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B*'s coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2*, the plan cannot rescind *B*'s coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

[80 FR 72277, Nov. 18, 2015]

§ 147.130 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§147.131, 147.132, and 147.133, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, co-insurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§147.131, 147.132, and 147.133; and

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19)

and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.

(2) *Office visits.* (i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

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

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a

rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1*. As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers.* (i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the

frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing.* (1) A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued, except as provided in paragraph (b)(3) of this section.

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the applicable plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market,

policy year), or as otherwise provided in paragraph (b)(3) of this section, is downgraded to a “D” rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a Federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the applicable plan or policy year.

(3) *Rapid coverage of preventive services for coronavirus.* In the case of a qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, a plan or issuer must provide coverage for such item, service, or immunization in accordance with this section by the date that is 15 business days after the date on which a recommendation specified in paragraph (a)(1)(v)(A) or (B) of this section is made relating to such item, service, or immunization.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* §147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

(e) *Sunset date.* The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, as

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a result of COVID-19, including any subsequent renewals of that determination.

[75 FR 41759, July 19, 2010, as amended at 76 FR 46626, Aug. 3, 2011; 78 FR 39896, July 2, 2013; 80 FR 41346, July 14, 2015; 82 FR 47833, 47861, Oct. 13, 2017; 85 FR 71202, Nov. 6, 2020]

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

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

(1) The organization is an objecting entity described in §147.132(a)(1)(i) or (ii), or 45 CFR 147.133(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under §147.132(a) or §147.133, the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule.* If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and §147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to

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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

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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 max-

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imum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[82 FR 47833, Oct. 13, 2017, as amended at 82 FR 47861, Oct. 13, 2017; 83 FR 57589, Nov. 15, 2018]

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities*. (1) Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines’ requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan

sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object

as specified in this paragraph (b), and nothing in §147.130(a)(1)(iv), 26 CFR 54.9815-2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of §147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[82 FR 47835, Oct. 13, 2017, as amended at 83 FR 57590, Nov. 15, 2018]

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the

group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in §147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition.* For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[82 FR 47861, Oct. 13, 2017, as amended at 83 FR 57630, Nov. 15, 2018]

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions—(1) Scope—(i) In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health

plans, as defined under § 147.140. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, non-emergency services performed by non-participating 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 require-

ments 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)—

(I) 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).

(I) 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)—

(I) 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).

(I) 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 enti-

tled 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 ex-

ternal 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, bene-

ficiaries, 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)(i)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

Example 3 —(i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under §149.110 do not apply because the treatment did not involve "emergency services" within the meaning of §149.110(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3*, the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with §149.110. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 4 —(i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under §149.120. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if

cost sharing had been calculated in a manner consistent with the requirements of §149.120.

(ii) *Conclusion.* In this *Example 4*, whether the plan was required to decide the claim in a manner consistent with the requirements of §149.120 involves considering whether the plan complied with §149.120, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5 —(i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under §149.110(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with §149.110.

(ii) *Conclusion.* In this *Example 5*, whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under §149.110(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6 —(i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a non-participating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under §149.120(a) and the fact that those protections may not be waived for neonatology services under §149.120(b).

(ii) *Conclusion.* In this *Example 6*, medical judgment is necessary to determine whether the correct code was used and compliance with §149.120(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note

that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7 —(i) *Facts*. A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under §149.120(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under §149.120(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with §149.120(a) and (b).

(ii) *Conclusion*. In this *Example 7*, consideration of whether the plan complied with the requirements in §149.120(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(2) *External review process standards*. The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2)) if such process provides the following.

(i) *Request for external review*. A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the

request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general*. Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(1) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(2) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.*, worker classification or similar determination);

(3) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(4) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general*. The group health plan or health insurance issuer

must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(1) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(2) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(3) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(4) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(1) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(2) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(3) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and in-

formation, 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

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(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans and grandfathered individual market policies, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

[80 FR 72278, Nov. 18, 2015, as amended at 86 FR 56122, Oct. 7, 2021]

§ 147.138 Patient protections.

(a) *Choice of health care professional—*
(1) *Designation of primary care provider—*
(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary

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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 obstet-

rical 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

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average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize*, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning before January 1, 2022. *See also* subparts B and D of part 149 of this subchapter for rules applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

[80 FR 72286, Nov. 18, 2015, as amended at 86 FR 36970, July 13, 2021]

45 CFR Subtitle A (10–1–24 Edition)

§ 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 em-

ployers 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% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). The maximum percentage increase permitted is 37.69% ($0.2269 = 22.69\%$; $22.69\% + 15\% = 37.69\%$). Because 33.33% does not exceed

37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3* 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% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% ($0.2527 = 25.27\%$; $25.27\% + 15\% = 40.27\%$), or \$6.26 ($5 \times 0.2527 = \1.26; $\$1.26 + \$5 = \$6.26$). Because 50% exceeds 40.27% and \$15 exceeds \$6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* 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% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). 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% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). 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 \times 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 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 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

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family coverage. The required employee contribution for the coverage is \$1,000 for self-only coverage and \$4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% $((5,000 - 1,000)/5,000)$ for self-only coverage and 67% $((12,000 - 4,000)/12,000)$ for family coverage. For a subsequent plan year, the COBRA premium is \$6,000 for self-only coverage and \$15,000 for family coverage. The employee contributions for that plan year are \$1,200 for self-only coverage and \$5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% $((6,000 - 1,200)/6,000)$ for self-only coverage and 67% $((15,000 - 5,000)/15,000)$ for family coverage.

(ii) *Conclusion.* In this *Example 9*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 10. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 10*, the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

Example 11. (i) *Facts.* A group health plan that is a grandfathered health plan and also a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code had a \$2,400 deductible for family coverage on March 23, 2010. The plan is subsequently amended after June 15, 2021 to increase the deductible limit by the amount that is necessary to comply with the requirements for a plan to qualify as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code, but that exceeds the maximum percentage increase.

(ii) *Conclusion.* In this *Example 11*, the increase in the deductible at that time does not cause the plan to cease to be a grandfathered health plan because the increase was necessary for the plan to continue to satisfy the definition of a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

[80 FR 72289, Nov. 18, 2015, as amended at 85 FR 81120, Dec. 15, 2020]

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§ 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 re-

quirements with respect to specified recommended preventive services.

[77 FR 16468, Mar. 21, 2012, as amended at 78 FR 13439, Feb. 27, 2013; 79 FR 13834, Mar. 11, 2014; 81 FR 12334, Mar. 8, 2016]

§ 147.150 Coverage of essential health benefits.

(a) *Requirement to cover the essential health benefits package.* A health insurance issuer offering health insurance coverage in the individual or small group market must ensure that such coverage includes the essential health benefits package as defined in section 1302(a) of the Affordable Care Act effective for plan or policy years beginning on or after January 1, 2014.

(b) *Cost-sharing under group health plans.* [Reserved]

(c) *Child-only plans.* If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d)(1) of the Affordable Care Act, the issuer must offer coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

[78 FR 12865, Feb. 25, 2013]

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

(a) *In general.* The provisions of §146.136 of this subchapter apply to health insurance coverage offered by health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after the applicability dates set forth in §146.136(i) of this subchapter. This section applies to non-grandfathered and grandfathered health plans as defined in §147.140.

[78 FR 68296, Nov. 13, 2013]

EFFECTIVE DATE NOTE: At 89 FR 77751, Sept. 23, 2024, §147.160 was revised, effective Nov. 22, 2024. For the convenience of the user, the revised text is set forth as follows:

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

(a) *In general.* The provisions of §§ 146.136 and 146.137 of this subchapter apply to individual health insurance coverage offered by a health insurance issuer in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after January 1, 2026. Until the applicability date in the preceding sentence, issuers are required to continue to comply with 45 CFR 147.160, incorporating 45 CFR 146.136, each revised as of October 1, 2023. This section applies to non-grandfathered and grandfathered health plans as defined in § 147.140.

§ 147.200 Summary of benefits and coverage and uniform glossary.

(a) *Summary of benefits and coverage—*
(1) *In general.* A group health plan (and its administrator as defined in section 3(16)(A) of ERISA), and a health insurance issuer offering group or individual health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for each benefit package without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section.

(i) *SBC provided by a group health insurance issuer to a group health plan—*
(A) *Upon application.* A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application for health coverage, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application. If an SBC was provided before application pursuant to paragraph (a)(1)(i)(D) of this section (relating to SBCs upon request), this paragraph (a)(1)(i)(A) is deemed satisfied, provided there is no change to the information required to be in the SBC. However, if there has been a change in the information required, a new SBC that includes the changed information must be provided upon application pursuant to this paragraph (a)(1)(i)(A).

(B) *By first day of coverage (if there are changes).* If there is any change in the information required to be in the SBC that was provided upon application and

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before the first day of coverage, the issuer must update and provide a current SBC to the plan (or its sponsor) no later than the first day of coverage.

(C) *Upon renewal, reissuance, or re-enrollment.* If the issuer renews or reissues a policy, certificate, or contract of insurance for a succeeding policy year, or automatically re-enrolls the policyholder or its participants and beneficiaries in coverage, the issuer must provide a new SBC as follows:

(1) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date the written application materials are distributed.

(2) If renewal, reissuance, or reenrollment is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year; however, with respect to an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) *Upon request.* If a group health plan (or its sponsor) requests an SBC or summary information about a health insurance product from a health insurance issuer offering group health insurance coverage, an SBC must be provided as soon as practicable, but in no event later than seven business days following receipt of the request.

(ii) *SBC provided by a group health insurance issuer and a group health plan to participants and beneficiaries—*
(A) *In general.* A group health plan (including its administrator, as defined under 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:

(I) 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

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in paragraph (a)(4)(ii) or (iii) of this section.

(5) *Language.* A group health plan or health insurance issuer must provide the SBC in a culturally and linguistically appropriate manner. For purposes of this paragraph (a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of §147.136(e) are met as applied to the SBC.

(b) *Notice of modification.* If a group health plan, or health insurance issuer offering group or individual health insurance coverage, makes any material modification (as defined under section 102 of ERISA) in any of the terms of the plan or coverage that would affect the content of the SBC, that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees (or, in the case of individual market coverage, an individual covered under a health insurance policy) not later than 60 days prior to the date on which the modification will become effective. The notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section.

(c) *Uniform glossary*—(1) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, must make available to participants and beneficiaries, and a health insurance issuer offering individual health insurance coverage must make available to applicants, policyholders, and covered dependents, the uniform glossary described in paragraph (c)(2) of this section in accordance with the appearance and form and manner requirements of paragraphs (c)(3) and (4) of this section.

(2) *Health-coverage-related terms and medical terms.* The uniform glossary must provide uniform definitions, specified by the Secretary in guidance, of the following health-coverage-related terms and medical terms:

(i) Allowed amount, appeal, balance billing, co-insurance, complications of pregnancy, co-payment, deductible, durable medical equipment, emergency medical condition, emergency medical

transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, in-network co-insurance, in-network co-payment, medically necessary, network, non-preferred provider, out-of-network coinsurance, out-of-network co-payment, out-of-pocket limit, physician services, plan, preauthorization, preferred provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, rehabilitation services, skilled nursing care, specialist, usual customary and reasonable (UCR), and urgent care; and

(ii) Such other terms as the Secretary determines are important to define so that individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in guidance.

(3) *Appearance.* A group health plan, and a health insurance issuer, must provide the uniform glossary with the appearance specified by the Secretary in guidance to ensure the uniform glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee (or, in the case of individual market coverage, an average individual covered under a health insurance policy).

(4) *Form and manner.* A plan or issuer must make the uniform glossary described in this paragraph (c) available upon request, in either paper or electronic form (as requested), within seven business days after receipt of the request.

(d) *Preemption.* For purposes of this section, the provisions of section 2724 of the PHS Act continue to apply with respect to preemption of State law. State laws that conflict with this section (including a state law that requires a health insurance issuer to provide an SBC that supplies less information than required under paragraph (a) of this section) are preempted.

(e) *Failure to provide.* A health insurance issuer or a non-federal governmental health plan that willfully fails to provide information to a covered individual required under this section is

subject to a fine of not more than \$1,000 as adjusted annually under 45 CFR part 102 for each such failure. A failure with respect to each covered individual constitutes a separate offense for purposes of this paragraph (e). HHS will enforce these provisions in a manner consistent with §§150.101 through 150.465 of this subchapter.

(f) *Applicability to Medicare Advantage benefits.* The requirements of this section do not apply to a group health plan benefit package that provides Medicare Advantage benefits pursuant to or 42 U.S.C. Chapter 7, Subchapter XVIII, Part C.

(g) *Applicability date.* (1) This section is applicable to group health plans and group health insurance issuers in accordance with this paragraph (g). (See §147.140(d), providing that this section applies to grandfathered health plans.)

(i) For disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), this section applies beginning on the first day of the first open enrollment period that begins on or after September 1, 2015; and

(ii) For disclosures with respect to participants and beneficiaries who enroll in coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), this section applies beginning on the first day of the first plan year that begins on or after September 1, 2015.

(2) For disclosures with respect to plans, this section is applicable to health insurance issuers beginning September 1, 2015.

(3) For disclosures with respect to individuals and covered dependents in the individual market, this section is applicable to health insurance issuers beginning with respect to SBCs issued for coverage that begins on or after January 1, 2016.

[80 FR 34310, June 16, 2015, as amended at 81 FR 61581, Sept. 6, 2016]

§ 147.210 Transparency in coverage—definitions.

(a) *Scope and definitions.*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health in-

surance issuers in the individual and group markets established in this section and §§147.211 and 147.212.

(2) *Definitions.* For purposes of this section and §§147.211 and 147.212, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant, beneficiary, or enrollee has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant, beneficiary, or enrollee has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant, beneficiary, or enrollee has used within that time period).

(ii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify

health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(iv) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant, beneficiary, or enrollee for a specific treatment or procedure.

(v) *Copayment assistance* means the financial assistance a participant, beneficiary, or enrollee receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) *Cost-sharing liability* means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant, beneficiary, or enrollee with respect to health care benefits that are relevant to a determination of the participant's, beneficiary's, or enrollee's cost-sharing liability for a particular covered item or service.

(viii) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers or submitting data in accordance with

the requirements of §153.710(c) of this subchapter.

(x) *Enrollee* means an individual who is covered under an individual health insurance policy as defined under section 2791(b)(5) of the Public Health Service (PHS) Act.

(xi) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with §147.212. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under §147.212(b)(1)(iii)(D)(3).

(xii) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee.

(xiii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in

connection with the provision of health care.

(xiv) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xvi) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvii) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xviii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's, beneficiary's, or enrollee's group health plan or health insurance coverage to provide items or services.

(xix) *Out-of-pocket limit* means the maximum amount that a participant, beneficiary, or enrollee is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xx) *Plain language* means written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.

(xxi) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or

other forms of medical management techniques.

(xxii) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

[85 FR 72305, Nov. 12, 2020]

§ 147.211 Transparency in coverage—required disclosures to participants, beneficiaries, or enrollees.

(a) *Scope and definitions*—(1) *Scope*. This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions*. For purposes of this section, the definitions in § 147.210 apply.

(b) *Required disclosures to participants, beneficiaries, or enrollees*. At the request of a participant, beneficiary, or enrollee who is enrolled in a group health plan or health insurance issuer offering group or individual health insurance coverage, the plan or issuer must provide to the participant, beneficiary, or enrollee the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information*. The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's, beneficiary's, or enrollee's cost-sharing liability for covered items and services:

(i) An estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for a requested covered item or service furnished by a provider or providers, which must reflect any cost-sharing reductions the enrollee would receive, that is calculated based on the

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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:

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(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 pro-

vided by a specific in-network provider or by all in-network providers by inputting:

(1) A billing code (such as CPT code 87804) or a descriptive term (such as "rapid flu test"), at the option of the user;

(2) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(3) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(1) A billing code or descriptive term, at the option of the user; and

(2) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's, beneficiary's, or enrollee's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant, beneficiary, or enrollee. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant, beneficiary, or enrollee;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants, beneficiaries, and enrollees request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or

issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(2) As provided under §147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in §147.126(d)(6) or short term limited duration insurance as defined in 45 CFR 144.103.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to

comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[85 FR 72305, Nov. 12, 2020]

§ 147.212 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in § 147.210 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs.* A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information.* Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimburse-

ment 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

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comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[85 FR 72305, Nov. 12, 2020]

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

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AUTHORITY: 42 U.S.C. 300gg through 300gg-63, 300gg-11 300gg-91, and 300-gg92, as amended.

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

Subpart A—General Provisions

§ 148.101 Basis and purpose.

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to guarantee the renewability of all coverage in the individual market. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth and protects all individuals and family members who have, or seek, individual health insurance coverage