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Final Rules for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections Under the Affordable Care Act; Final Rules

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 54**

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1545–BJ57**DEPARTMENT OF LABOR****Employee Benefits Security
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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****45 CFR Parts 144, 146 and 147**

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**Final Rules for Grandfathered Plans,
Preexisting Condition Exclusions,
Lifetime and Annual Limits,
Rescissions, Dependent Coverage,
Appeals, and Patient Protections
Under the Affordable Care Act**

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document contains final regulations regarding grandfathered health plans, preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, coverage of dependent children to age 26, internal claims and appeal and external review processes, and patient protections under the Affordable Care Act. It finalizes changes to the proposed and interim final rules based on comments and incorporates subregulatory guidance issued since publication of the proposed and interim final rules.

DATES:

Effective date. These final regulations are effective on January 19, 2016.

Applicability date. These final regulations apply to group health plans and health insurance issuers beginning on the first day of the first plan year (or, in the individual market, the first day of the first policy year) beginning on or after January 1, 2017. For information on requirements applicable prior to this date, see section II.I. of this preamble.

FOR FURTHER INFORMATION CONTACT:

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Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor’s Web site (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS’s Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010 (these are collectively known as the “Affordable Care Act”). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term “group health plan” includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated into the Code and ERISA are sections 2701 through 2728.

The Departments of Labor (DOL), Health and Human Services (HHS) and the Treasury (collectively, the Departments) have issued regulations implementing the revised PHS Act sections 2701 through 2719A in several

phases.² Throughout 2010, the Departments issued interim final regulations (or temporary and proposed regulations),³ with requests for comment, implementing Affordable Care Act section 1251 (preservation of right to maintain existing coverage), and PHS Act sections 2704 (prohibition of preexisting condition exclusions), 2711 (prohibition on lifetime or annual limits), 2712 (prohibition on rescissions), 2714 (extension of dependent coverage), 2719 (internal claims and appeals and external review process), and 2719A (patient protections) (collectively, the 2010 interim final regulations). As discussed in more detail below, after consideration of comments⁴ in response to the 2010 interim final regulations, the Departments are issuing these final regulations.

II. Overview of the Final Regulations

A. Section 1251 of the Affordable Care Act, Preservation of Right To Maintain Existing Coverage (26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140)

Section 1251 of the Affordable Care Act provides that certain group health plans and health insurance coverage existing as of March 23, 2010 (the date of enactment of the Affordable Care Act) (grandfathered health plans) are only subject to certain provisions of the Affordable Care Act (for as long as they maintain that status as grandfathered health plans under the applicable regulations).⁵ On June 17, 2010, the Departments issued interim final regulations implementing section 1251 and requesting comment.⁶ On

² Note, however, that in sections under headings listing only two of the three Departments, the term “Departments” generally refers only to the two Departments listed in the heading.

³ The Departments of Labor and HHS published their rules as interim final rules and are finalizing their interim final rules. The Department of the Treasury/Internal Revenue Service published temporary regulations and proposed regulations with the text of the temporary regulations serving as the text of the proposed regulations. The Department of the Treasury/Internal Revenue Service is finalizing its proposed rules.

⁴ In response to the 2010 interim final regulations, the Departments received many comments that relate to early implementation issues, many of which were addressed through subregulatory guidance (addressed more fully below). While the Departments acknowledge and have reviewed the comments provided in response to the 2010 interim final regulations, to the extent the issues presented are now moot, such comments are not explicitly addressed below.

⁵ For a list of the market reform provisions under title XXVII of the PHS Act, as added or amended by the Affordable Care Act and incorporated into ERISA and the Code, applicable to grandfathered health plans, visit <http://www.dol.gov/ebsa/pdf/grandfatherregtable.pdf>.

⁶ 75 FR 34538.

¹ The term “group health plan” is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term “health plan,” as used in other provisions of title I of the Affordable Care Act. The term “health plan” does not include self-insured group health plans.

November 17, 2010, the Departments issued an amendment to the interim final regulations to permit certain changes in policies, certificates, or contracts of insurance without loss of grandfathered status.⁷ Also in 2010, the Departments released Affordable Care Act Implementation Frequently Asked Questions (FAQs) Parts I, II, IV, V, and VI to answer questions related to maintaining a plan's status as a grandfathered health plan.⁸ After consideration of the comments and feedback received from stakeholders, the Departments are publishing these final regulations. As discussed in more detail below, these final regulations finalize the 2010 interim final regulations and amendment to the interim final regulations without substantial change and incorporate the clarifications issued thus far in subregulatory guidance.

1. Definition of Grandfathered Health Plan Coverage

Under the Affordable Care Act and paragraph (a)(1) of the interim final regulations implementing section 1251 of the Affordable Care Act, a group health plan or group or individual health insurance coverage is a grandfathered health plan with respect to individuals enrolled on March 23, 2010 (for as long as it maintains that status under the applicable regulations). The interim final regulations provided that a group health plan or coverage does not relinquish its grandfather status 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 at least one person (although not necessarily the same person) at all times since March 23, 2010. The interim final regulations also provided that the determination of grandfather status

under the rules is made separately with respect to each benefit package made available under a group health plan or health insurance coverage.

Some commenters requested clarification with respect to the meaning of the term "benefit package" including requesting further guidance regarding what coverage option features constitute separate benefit packages. In response to the comments, the Departments issued Affordable Care Act Implementation FAQs Part II Q2 to further clarify the application of the rules on a benefit-package-by-benefit-package basis.⁹ These final regulations continue to provide that the determination of grandfather status applies separately with respect to each benefit package and incorporate the clarifications issued in the FAQs. Therefore, as demonstrated by the example provided in the FAQs, if a group health plan offers three benefit package options—a PPO (preferred provider organization), a POS (point of service) arrangement, and an HMO (health maintenance organization)—the PPO, POS arrangement, and HMO are treated as separate benefit packages. Similarly, under these final regulations, if any benefit package ceases grandfather status, it will not affect the grandfather status of the other benefit packages.

2. Disclosure of Grandfather Status

Paragraph (a)(2) of the interim final regulations implementing section 1251 of the Affordable Care Act provided that to maintain status as a grandfathered health plan, a plan or health insurance coverage (1) must include a statement, in any plan materials provided to participants or beneficiaries (in the individual market, primary subscribers) describing the benefits provided under the plan or health insurance coverage, that the plan or health insurance coverage believes that it is a grandfathered health plan within the meaning of section 1251 of the Affordable Care Act and (2) must provide contact information for questions and complaints. The interim final regulations provided model language that can be used to satisfy this disclosure requirement.¹⁰

The Departments received several comments asking the Departments to require enhanced disclosure to participants that includes a more comprehensive explanation of

grandfathered health plan status, information on the triggers that can result in a cessation of such status, a complete listing of the specific market reforms that are inapplicable to the plan by virtue of its status, and access to a formal process for obtaining a determination on a plan's status from the appropriate government agency. Other commenters stated that including this disclosure requirement in consumer materials may be confusing to participants, may not have the intended benefit, and that it may be more appropriate to include the applicable consumer protections in the employer plan documents or insurance coverage documents. Additional commenters stated this requirement is unnecessary because ERISA's disclosure requirements are already sufficient to explain to participants the information they need about their plan (including which benefits are included or excluded), and that including information about what benefits they could have had if their employers chose to relinquish their grandfathered plan status is unnecessary.

In response to these comments the Departments issued Affordable Care Act Implementation FAQs Part IV Q1, in which the Departments clarified that a grandfathered health plan is not required to provide the disclosure statement every time it sends out a communication, such as an explanation of benefits (EOB), to a participant or beneficiary. Instead, a grandfathered health plan will comply with this disclosure requirement if it includes the model disclosure language provided in the Departments' interim final grandfather regulations (or a similar statement) whenever a summary of the benefits under the plan is provided to participants and beneficiaries. For example, many plans distribute summary plan descriptions upon initial eligibility to receive benefits under the plan or coverage, during an open enrollment period, or upon other opportunities to enroll in, renew, or change coverage. The FAQs also provided that, while it is not necessary to include the disclosure statement with each plan or issuer communication to participants and beneficiaries (such as an EOB), the Departments encourage plan sponsors and issuers to identify other communications in which disclosure of grandfather status would be appropriate and consistent with the goal of providing participants and beneficiaries information necessary to

⁷ 75 FR 70114.

⁸ See Affordable Care Act Implementation FAQs Part I, available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html, Affordable Care Act Implementation FAQs Part II available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html, Affordable Care Act Implementation FAQs Part IV, available at <http://www.dol.gov/ebsa/faqs/faq-aca4.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html and Affordable Care Act Implementation FAQs Part V, available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html and Affordable Care Act Implementation FAQs Part VI, available at <http://www.dol.gov/ebsa/faqs/faq-aca6.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.

⁹ See Affordable Care Act Implementation FAQs Part II, available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

¹⁰ 29 CFR 2590.715-1251(a)(2)(ii); 45 CFR 147.140(a)(2)(ii).

understand and make informed choices regarding health coverage.¹¹

After consideration of the comments and feedback from stakeholders, the Departments retain the approach in the interim final regulations and subsequent subregulatory guidance because that approach provides consumers with information about the status of their plan or health insurance coverage, which assists them in identifying and enforcing their rights, without undue burden on plans and issuers. Therefore, these final regulations clarify that, to maintain status as a grandfathered health plan, a group health plan, or health insurance coverage, must include a statement that the plan or health insurance coverage believes it is a grandfathered health plan in any summary of benefits provided under the plan. It must also provide contact information for questions and complaints. These final regulations also retain the model disclosure language. Plans and issuers may (but are not required to) utilize the model disclosure language to satisfy this disclosure requirement. The Departments also note that the disclosure language is a model, and, thus, plans and issuers are permitted to include additional disclosure elements, such as the entire list of the market reform provisions that do not apply to grandfathered health plans.

3. Anti-Abuse Rules

The interim final regulations provided that a group health plan that provided coverage on March 23, 2010 generally is a grandfathered health plan with respect to new employees (whether newly hired or newly enrolled) and their families who enroll in the grandfathered health plan after March 23, 2010. The interim final regulations also provided two anti-abuse rules to curtail attempts to retain grandfather status by indirectly making changes that would otherwise result in a loss of grandfather status.

The first anti-abuse rule provided that 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. Under the second anti-abuse rule, the interim final regulations set forth specific criteria that, if met, would cause a plan that is transferring employees to relinquish its grandfather status. Specifically, the interim final regulations provided that a

plan that is transferring employees would relinquish its grandfather status if, 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, such amendment would cause a loss of grandfather status and there was no bona fide employment-based reason to transfer the employees into the transferee plan. The second anti-abuse rule was designed to prevent a plan or issuer from circumventing the limits on changes that cause a plan or health insurance coverage to cease to be a grandfathered health plan. This rule was intended to address situations in which employees who previously were covered by a grandfathered health plan are transferred to another grandfathered health plan without any bona fide employment-based reason.

a. Bona Fide Employment-Based Reasons

The Departments received several comments regarding the anti-abuse provisions. Stakeholders requested that the Departments clarify what constitutes a bona fide employment-based reason that would prevent a plan that is transferring employees from relinquishing its grandfather status. In response, the Departments issued Affordable Care Act Implementation FAQs Part VI Q1, which provided several examples of the variety of circumstances that would constitute a bona fide employment-based reason to transfer employees. Examples of a bona fide employment-based reason include: When a benefit package is being eliminated because the issuer is exiting the market; when a benefit package is being eliminated because the issuer no longer offers the product to the employer; 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; when a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or 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.¹²

These final regulations include those examples of bona fide employment-based reasons. The Departments continue to interpret the term “bona

fide employment-based reason” to embrace a variety of circumstances, and plans and issuers should evaluate all facts and circumstances carefully to determine whether a bona fide employment-based reason exists when considering transferring employees from one grandfathered health plan to another. The Departments may issue additional guidance if further questions regarding what constitutes a bona fide employment-based reason arise.

b. Clarification Regarding Multiemployer Plans

Section 1251 of the Affordable Care Act, as well as the 2010 interim final regulations, permit a grandfathered group health plan to cover new employees without any effect on its status as a grandfathered plan. Several commenters requested that the Departments clarify in the final regulations whether a multiemployer plan may add new contributing employers to the plan without triggering a loss of grandfather status. These final regulations clarify that 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 grandfathered status, provided that the multiemployer plan has not made any other changes that would cause the plan to relinquish its grandfathered status.

4. Maintenance of Grandfather Status

The interim final regulations set forth rules for determining when changes to the terms of a plan or health insurance coverage cause the plan or coverage to cease to be a grandfathered health plan. Specifically, the interim final regulations outlined six changes to benefits, cost-sharing mechanisms, and contribution rates that will cause a plan or health insurance coverage to relinquish its grandfather status.¹³ Since

¹³ The six changes (measured from March 23, 2010) outlined in paragraph (g)(1) of the interim final regulations that are considered to change a health plan so significantly that they will cause a group health plan or health insurance coverage to relinquish grandfather status include the following: (1) The elimination of all or substantially all benefits to diagnose or treat a particular condition, (2) any increase in percentage cost-sharing requirements, (3) an increase in a deductible or out-of-pocket maximum by an amount that exceeds medical inflation plus 15 percentage points, (4) an increase in a copayment by an amount that exceeds medical inflation plus 15 percentage points (or, if greater, \$5 plus medical inflation), (5) a decrease in an employer’s contribution rate towards the cost of coverage by more than 5 percentage points, or (6) the imposition of annual dollar limits below the restricted annual dollar limits that were in effect prior to 2014 (note that for plan years (or policy years in the individual market) beginning on and after January 1, 2014, annual dollar limits on

¹¹ See Affordable Care Act Implementation FAQs Part IV, available at <http://www.dol.gov/ebsa/faqs/faq-aca4.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html.

¹² See Affordable Care Act Implementation FAQs Part VI, available at <http://www.dol.gov/ebsa/faqs/faq-aca6.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.

the promulgation of the interim final regulations, questions have been brought to the Departments' attention regarding other specific changes to a plan's design and the impact of such changes on a plan's grandfather status.

a. Elimination of All or Substantially All Benefits

The 2010 interim final regulations and these final regulations provide that the elimination of all or substantially all benefits to diagnose or treat a particular condition will cause a group health plan or health insurance coverage to relinquish its grandfathered status. One commenter requested that the Departments clarify what constitutes eliminating "substantially all benefits" to diagnose or treat a particular condition. As the interim final regulations stated, and these final regulations continue to provide, 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. The Departments decline to establish a bright-line test establishing what constitutes "substantially all benefits" for purposes of these final regulations. Whether or not a plan 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 covered for a particular condition under the plan on March 23, 2010, as compared to the items and services covered at the time the plan makes the benefit change effective. The preamble to the 2010 interim final regulations provided two examples. First, if a plan or health insurance coverage eliminates all benefits for cystic fibrosis, the plan or coverage will lose its grandfathered status. Second, if a plan or insurance coverage provides benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs, and subsequently eliminates benefits for counseling, the plan is treated as having eliminated all or substantially all benefits for that mental health condition and will as a result lose its grandfathered status. These final regulations continue to provide that the elimination of all or substantially all benefits to diagnose or treat a particular condition will cause a group health plan or health insurance coverage to

essential health benefits are prohibited, except for grandfathered individual health insurance coverage). See 26 CFR 54.9815-1251(g), 29 CFR 2590.715-1251(g), and 45 CFR 147.140(g).

relinquish its grandfathered status and contain an example.

b. Increase in Fixed-Amount Copayments

The interim final regulations provided standards for when increases in fixed-amount copayments would cause a plan or coverage to relinquish its grandfather status. Under the interim final regulations, a plan or coverage ceases to be a grandfathered health plan if there is an increase since March 23, 2010 in a copayment that exceeds the greater of the maximum percentage increase¹⁴ or five dollars increased by medical inflation.¹⁵

With respect to grandfathered health plans that utilize multiple levels of copayments for different benefits under the plan, stakeholders sought clarification on what degree of change would cause a plan to relinquish its grandfather status. Specifically, stakeholders wanted to know whether raising the copayment level for a category of services by an amount that would otherwise trigger a loss of grandfather status would cause a loss of grandfather status if the plan retained the level of copayment on other categories of services. The Departments clarified in Affordable Care Act Implementation FAQs Part II Q4 that a change to a copayment level for a category of services that exceeds the standards set forth in the interim final regulations will cause a plan to relinquish its grandfather status, even if a plan retains the level of copayment for other categories of services.¹⁶ These final regulations retain this clarification, and continue to provide that each change in cost sharing must be separately evaluated under the standards set forth in the regulations. A plan or issuer may not exceed the standards set forth in these final regulations with respect to one level of copayment for a category of services, and retain its grandfather status by retaining the level of copayments for other categories of services.

¹⁴ The interim final regulations defined the maximum percentage increase as medical inflation (from March 23, 2010) plus 15 percentage points. Medical inflation is defined in the interim final regulations by reference to the overall medical care component of the Consumer Price Index for All Urban Consumers, unadjusted (CPI), published by the Department of Labor. See 26 CFR 54.9815-1251(g)(3), 29 CFR 2590.715-1251(g)(3), and 45 CFR 147.140(g)(3).

¹⁵ 75 FR 35538, 34543 (June 17, 2010).

¹⁶ See Affordable Care Act Implementation FAQs Part II, available at <http://www.dol.gov/ebsa/faqs/fq-aca2.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

c. Decrease in Contribution Rate by Employers and Employee Organization

The interim final regulations provided that a decrease in the employer contribution rate for coverage under a group health plan or group health insurance coverage beyond the permitted percentage would result in cessation of grandfather status. There are two rules related to decreases in employer contributions: One for a contribution based on the cost of coverage and one for a contribution based on a formula.

First, if the contribution rate is based on the 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 towards the cost of any tier of coverage for any class of similarly situated individuals¹⁷ by more than 5 percentage points below the contribution rate on March 23, 2010. For this purpose, contribution rate is defined as the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The interim final regulations also provided that the total cost of coverage is determined in the same manner as the applicable premium is calculated under the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Code, and section 2204 of the PHS Act. In the case of a self-insured group health plan, contributions by an employer or employee organization are calculated by subtracting the employee contributions towards the total cost of coverage from the total cost of coverage.

Second, if the contribution rate is based on a formula, such as hours worked or tons of coal mined, 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 towards the cost of any tier of coverage for any class of similarly situated individuals by more than 5 percentage points below the contribution rate on March 23, 2010. These final regulations finalize these provisions without change but incorporate the additional clarifications issued in subregulatory guidance as discussed below.

The Departments received several comments relating to the employer

¹⁷ Similarly situated individuals are described in the HIPAA nondiscrimination regulations at 26 CFR 54.9802-1(d), 29 CFR 2590.702(d), and 45 CFR 146.121(d).

contribution limitations. Some commenters stated that issuers do not always have the information needed to know whether (or when) an employer plan sponsor changes its rate of contribution towards the cost of group health plan coverage. In response to this issue, the Departments issued Affordable Care Act Implementation FAQs Part I Q2 and Q3 providing relief if issuers and employer plan sponsors or contributing employers and multiemployer plans take certain steps to communicate regarding changes to the contribution rate for purposes of determining grandfather status.¹⁸ These final regulations also provide relief to issuers, plan sponsors, employers, and plans that take certain steps to communicate changes in contribution rates. Specifically, these final regulations provide that an insured group health plan that is a grandfathered health plan will not relinquish its grandfather status immediately based on a change in the employer contribution rate if, upon renewal, an issuer requires a plan sponsor to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer does not already have it). Additionally, the issuer's policies, certificates, or contracts of insurance must disclose in a prominent and effective manner that plan sponsors are required to notify the issuer if the contribution rate changes at any point during the plan year. An insured grandfathered group health plan with a decrease in employer contributions relinquishes its grandfather status as of the earlier of the first date on which the issuer knows or reasonably should know that there has been at least a 5-percentage-point reduction or the first date on which the plan no longer qualifies for grandfathered status without regard to the 5-percentage-point reduction. Similarly, if multiemployer plans and contributing employers follow these steps, the plan will not relinquish its grandfather status unless or until the multiemployer plan knows or reasonably should know that the contribution rate has changed by at least the applicable 5-percentage point reduction or until the date the plan no longer qualifies for grandfathered status without regard to the 5-percentage point reduction. Moreover, nothing in the Affordable Care Act or these regulations

¹⁸ See Affordable Care Act Implementation FAQs Part I, available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.

prevents a policy, certificate, or contract of insurance from requiring a plan sponsor to notify an issuer in advance (for example, 30 or 60 days in advance) of a change in their contribution rate.

The Departments also received comments on the application of this provision to multiemployer plans with unique contribution structures. It is common for multiemployer plans to have either a fixed-dollar employee contribution or no employee contribution towards the cost of coverage. In such cases, a contributing employer's contribution rate may change (for example, after making up a funding deficit in the prior year or to reflect a surplus) but the employee contribution amount is not affected. The Departments issued Affordable Care Act Implementation FAQs Part I Q4 clarifying that in this case, provided any changes in the coverage terms would not otherwise cause the plan to cease to be grandfathered and there continues to be no employee contribution or no increase in the fixed-dollar employee contribution towards the cost of coverage, the plan would not relinquish its grandfather status.¹⁹ These final regulations incorporate this clarification and apply the relief to all grandfathered group health plans. Therefore, under these final regulations a group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan if the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage and there are no corresponding changes in coverage terms that would otherwise cause the plan to cease to be a grandfathered plan.

The Departments also received comments requesting clarification on the application of the rules where a group health plan includes multiple tiers of coverage. In response, the Departments issued Affordable Care Act Implementation FAQs Part II Q3, explaining that the standards for employer contributions found in paragraph (g)(1)(v) of the interim final regulations on grandfathered health plans apply on a tier-by-tier basis.²⁰

¹⁹ See Affordable Care Act Implementation FAQs Part I, available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.

²⁰ See Affordable Care Act Implementation FAQs Part II, available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

These final regulations incorporate this guidance. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.*, self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.*, at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage could not cause the plan to lose grandfather status.

The Departments also received comments asking for clarification on when a decrease in the employer contribution rate for coverage under a group health plan or group health insurance beyond the permitted percentage would result in cessation of grandfather status for a contribution based on a formula. In response, the Departments issued Affordable Care Act Implementation FAQs Part VI Q6.²¹ The FAQ provided an example under which a plan covers both retirees and active employees and the employer that sponsors the plan contributes \$300 per year multiplied by the individual's years of service for the employer, capped at \$10,000 per year. In the example, the employer makes contributions based on a formula, and accordingly, the plan will cease to be a grandfathered health plan if the employer decreases its contribution rate towards the cost of coverage by more than five percent below the contribution rate on March 23, 2010. If the formula does not change, the employer is not considered to have reduced its contribution rate, regardless of any

²¹ See Affordable Care Act Implementation FAQs Part VI, available at <http://www.dol.gov/ebsa/faqs/faq-aca6.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.

increase in the total cost of coverage. However, if the dollar amount that is multiplied by years of service decreases by more than five percent (or if the \$10,000 maximum employer contribution cap decreases by more than five percent), the plan will cease to be a grandfathered health plan. Although this example has not been added to the text of the final regulations, this guidance continues to apply.

d. Changes in Annual Limits

PHS Act section 2711, as added by the Affordable Care Act, generally prohibits lifetime and annual limits on the dollar amount of essential health benefits, as defined in section 1302(b) of the Affordable Care Act. Under PHS Act section 2711 and its implementing regulations, plans and issuers were generally prohibited from imposing lifetime limits on the dollar value of essential health benefits for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

With respect to annual dollar limits, for plan or policy years beginning before January 1, 2014, plans and issuers were permitted to impose restricted annual dollar limits in accordance with the guidance set forth in the interim final regulations. For plans years beginning on or after January 1, 2014, plans and issuers generally are prohibited from imposing annual dollar limits on essential health benefits. However, grandfathered individual health insurance plans are not subject to the annual dollar limit prohibition. Accordingly, the final regulations retain the rules regarding loss of grandfathered status based on imposition of annual dollar limits to allow issuers of grandfathered individual health insurance coverage to analyze grandfathered status.

These final regulations, like the interim final regulations, address three different limit-related situations that would cause a plan or health insurance coverage to relinquish its grandfather status: (1) A plan or 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; (2) A plan or 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; and (3) A plan or 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).

e. Changes to Fixed Amount Cost-Sharing Based on a Formula

On December 22, 2010, the Departments issued Affordable Care Act Implementation FAQs Part V Q7 to provide clarification on the application of the thresholds under paragraph (g)(1) of the interim final regulations when a plan's terms include out-of-pocket spending limits that are based on a formula.²² The Departments continue to interpret paragraph (g)(1) as clarified in the FAQ. Therefore, under these final regulations, if a plan or coverage has a fixed-amount cost-sharing requirement other than a copayment (for example, a deductible or out-of-pocket limit) that is based on a percentage-of-compensation formula, that cost-sharing arrangement will not cause the plan or coverage to cease to be a grandfathered health plan as long as the formula remains the same as that which was in effect on March 23, 2010. Accordingly, if the percentage-of-compensation formula for determining an out-of-pocket limit is unchanged and an employee's compensation increases, then the employee could face a higher out-of-pocket limit, but that change would not cause the plan to relinquish grandfather status.

f. Grandfather Status and Wellness Programs

Under PHS Act section 2705, ERISA section 702, and Code section 9802 and the Departments' implementing regulations, group health plans and health insurance issuers in the group and individual market are prohibited from discriminating against participants, beneficiaries, and individuals in eligibility, benefits, or premiums based on a health factor.²³

²² See Affordable Care Act Implementation FAQs Part V and Mental Health Parity Implementation, available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.

²³ The statute and its implementing regulations set forth eight health status-related factors, which the final regulations on Nondiscrimination and Wellness Programs in Health Coverage in the Group Market refer to as "health factors" for simplicity. 71 FR 75014, 75016 (Dec. 13, 2006) Under the statute

For group health plans and group health insurance coverage, an exception to this general prohibition allows premium discounts, rebates, or modification of otherwise applicable cost sharing (including copayments, deductibles, or coinsurance) in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs.

Many stakeholders requested clarification with respect to how changes to contribution rates and cost-sharing mechanisms in the context of a wellness program would impact a plan's grandfather status. In light of these questions, the Departments issued Affordable Care Act Implementation FAQs Part II Q5, which stated that while group health plans may continue to provide incentives for wellness by providing premium discounts or additional benefits to reward healthy behaviors by participants and beneficiaries, penalties (such as cost-sharing surcharges) may implicate the standards outlined in paragraph (g)(1) of the grandfather interim final regulations and should be examined carefully.²⁴ If additional questions arise regarding the interaction of wellness programs and these requirements, the Departments may issue additional subregulatory guidance.

g. Changes to Multi-Tiered Prescription Drug Formularies

In Affordable Care Act Implementation FAQs Part VI Q2, the Departments addressed questions related to certain changes to the level of cost sharing for brand-name prescription drugs. Stakeholders requested that the Departments clarify whether changes to cost sharing for brand-name prescription drugs would cause a plan to relinquish its grandfather status in instances where a plan classifies and determines cost sharing for prescription drugs based on the availability of a generic alternative, and a generic drug becomes available and is added to the formulary. The Departments stated that if a drug was classified in a tier as a brand name drug

and the regulations, the eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability. Id. In the Departments' view, "[t]hese terms are largely overlapping and, in combination, include any factor related to an individual's health." 66 FR 1378, 1379 (Jan. 8, 2001).

²⁴ See Affordable Care Act Implementation FAQs Part II, available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

with no generic available, and a generic alternative for the drug becomes available and is added to the formulary, moving the brand-name drug to a higher tier would not cause the plan or coverage to relinquish grandfather status.²⁵ These final regulations adopt this rule that such changes will not result in a loss of grandfather status.

h. Grandfather Status and Certain Changes in Individual Policies

Some individual health insurance policies in place on March 23, 2010 included a feature that allowed a policyholder to elect an option under which the individual would pay a reduced premium in exchange for higher cost sharing. The Departments received comments asking whether individuals enrolled in these policies as of March 23, 2010 could make such an election after March 23, 2010 without affecting the policy's grandfather status, even if the increase in cost sharing would exceed the limits set forth under the interim final regulations. In response, the Departments issued Affordable Care Act Implementation FAQs Part IV Q2, which stated that, as long as the policyholder had such option under the insurance policy that was in place on March 23, 2010, he or she could exercise the option after March 23, 2010 without affecting grandfather status, even if as a result of electing this option the individual's cost sharing would increase by an amount that exceeds the limits established under the interim final regulations.²⁶ The Departments maintain this approach in these final regulations.

i. Clarifications on Timing of the Loss of Grandfather Status

Since the promulgation of the 2010 interim final regulations, questions have arisen regarding whether or not a plan ceases to be a grandfathered health plan immediately after making a change that triggers a loss of grandfathered status, and whether or not there is an opportunity to cure a loss of grandfather status following a change made inadvertently or otherwise that triggers a loss of grandfather status. Several commenters have requested clarification on when the plan or coverage ceases to be a grandfathered health plan if it makes an amendment to plan terms that

trigger loss of grandfather status in the middle of the plan year. The Departments issued Affordable Care Act Implementation FAQs Part VI Q4 and Q5 addressing timing of the loss of grandfather status with respect to mid-year plan amendments that exceed the thresholds described in the interim final regulations.²⁷ These final regulations adopt the clarification outlined in the FAQs that a plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms that exceeds the thresholds described in paragraph (g)(1) of these final regulations becomes effective—regardless of when the amendment is adopted. Once grandfather status is lost there is no opportunity to cure the loss of grandfather status. A reversal after the effective date will not allow the plan or coverage to regain grandfather status. If a plan sponsor wishes to avoid relinquishing grandfathered status in the middle of a plan year, any changes that will cause a plan or coverage to relinquish grandfather status should not be effective before the first day of a plan year that begins after the change is adopted.

B. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108)

PHS Act section 2704, added by the Affordable Care Act, amends the HIPAA²⁸ rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage generally may not impose any preexisting condition exclusions.²⁹ HIPAA, as well as PHS Act section 2704 and its implementing regulations, define a preexisting condition exclusion as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage,

regardless of whether any medical advice, diagnosis, care, or treatment was recommended or received before that date. PHS Act section 2704,³⁰ which became effective for enrollees who are under 19 years of age for plan years (in the individual market, policy years) beginning on or after September 23, 2010, and effective for adults for plan years (in the individual market, policy years) beginning on or after January 1, 2014, prohibits preexisting condition exclusions for both group health plans and group or individual health insurance coverage (except for grandfathered individual health insurance). On June 28, 2010, the Departments issued interim final regulations implementing PHS Act section 2704 and requesting comment.³¹ After issuance of regulations in 2010, the Departments also released Affordable Care Act Implementation FAQs Part V, Q6³² to provide additional clarification on the prohibition of preexisting condition exclusions. These final regulations finalize the 2010 interim final regulations without substantial change and incorporate the clarifications issued to date in subregulatory guidance.

1. Allowable Exclusion of Benefits

Prior to implementation of PHS Act section 2704, HIPAA rules limiting preexisting condition exclusions provided that a plan's or issuer's exclusion of benefits for a condition regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. With respect to such exclusions, the 2010 interim final regulations did not change this approach under HIPAA.³³

Several commenters requested that the final regulations reiterate this rule. Other commenters requested that all exclusions of specific conditions be prohibited regardless of whether the exclusion relates to when the condition arose. Another commenter wrote that restrictions on benefits concerning

²⁵ Affordable Care Act Implementation FAQs Part VI, available at <http://www.dol.gov/ebsa/faqs/faq-aca6.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.

²⁶ See Affordable Care Act Implementation FAQs Part IV, available at <http://www.dol.gov/ebsa/faqs/faq-aca4.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html.

²⁷ See Affordable Care Act Implementation FAQs Part VI, available at <http://www.dol.gov/ebsa/faqs/faq-aca6.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.

²⁸ HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191).

²⁹ The HIPAA rules (that were in effect prior to the effective date of these amendments) applied only to group health plans and group health insurance coverage, and permitted limited exclusions of coverage based on a preexisting condition under certain circumstances. Section 2704 prohibits any preexisting condition exclusion from being imposed by group health plans or group health insurance coverage and extends this protection to non-grandfathered individual health insurance coverage but this prohibition does not apply to grandfathered individual health insurance coverage.

³⁰ Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1) was the applicable provision concerning preexisting condition exclusions; after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1) is the applicable provision. See also ERISA section 701(b)(1) and Code section 9801(b)(1).

³¹ 75 FR 37188 (June 28, 2010).

³² See Affordable Care Act Implementation FAQs Part V, available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.

³³ The rule is illustrated with examples in the HIPAA regulations on preexisting condition exclusions. See Examples 6, 7, and 8 in 26 CFR 54.9801–3(a)(2), 29 CFR 2590.701–3(a)(2), 45 CFR 146.111(a)(2).

rehabilitation services and devices should be considered a form of preexisting condition exclusion and not be allowed.

Similar to the interim final regulations, these final regulations retain the approach set forth under HIPAA relating to exclusions for a specific benefit. More specifically, these final regulations continue to provide that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. Other requirements of Federal or State law, however, may prohibit certain benefit exclusions, including the essential health benefits requirements applicable in the individual and small group health insurance markets at 45 CFR 156.110 *et seq.*

2. Enrollment Period

The 2010 interim final regulations did not impose any requirement on plans to provide for an open enrollment period. One commenter requested that the regulations clarify that issuers in the individual market may restrict enrollment of children under age 19 to specified open enrollment periods, consistent with guidance issued by HHS.³⁴ Another commenter requested that the regulations specify that after the initial enrollment period, health insurance issuers must make open enrollment periods available to families at least once a year during a standardized time period for at least 90 days and that insurers should fully advertise the availability. Another commenter stated that having at least one issuer that offers open enrollment at any time during the year, without a penalty for deferral, will be an economic incentive to defer the purchase of insurance which may encourage adverse selection and subsequently, higher claim costs. Additional commenters requested continuous open enrollment for children with preexisting conditions, clarification of whether guaranteed issue will be available only during open enrollment or all 12 months of the year, and that families be given the opportunity to enroll their children when certain life events occur. These final regulations do not adopt these suggestions. The provisions of the Affordable Care Act related to guaranteed availability of coverage,

³⁴ Center for Consumer Information & Insurance Oversight, Questions and Answers on Enrollment of Children Under 19 Under the New Policy That Prohibits Pre-Existing Condition Exclusions, available at <https://www.cms.gov/CCIIO/Resources/Files/factsheet.html>.

including open and special enrollment periods, are implemented in regulations issued by HHS under section 2702 of the PHS Act and are outside the scope of this rulemaking. Additionally, while HIPAA generally permits plans and issuers to treat participants and beneficiaries with adverse health factors more favorably, such as providing a longer open enrollment period, nothing in these regulations requires plans and issuers to do so.

3. Premiums

Commenters raised concerns about increasing premiums related to the prohibition on preexisting condition exclusions. Effective for plan years (or, in the individual market, policy years) beginning on or after January 1, 2014, section 2701 of the PHS Act and section 1312(c) of the Affordable Care Act govern the premium rates charged by an issuer for non-grandfathered health insurance coverage in the individual and small group markets, and section 2794 of the PHS Act provides for the annual review of unreasonable increases in premiums for health insurance coverage in the individual and small group markets. These provisions are implemented in regulations issued by HHS³⁵ and are outside the scope of this rulemaking. However, the rating rules under PHS Act section 2701 prohibit variations in premiums based on a child's health status.

4. Allowable Screenings To Determine Eligibility for Alternative Coverage in the Individual Market

Subsequent to the promulgation of the interim final regulations, questions arose regarding whether it would be permissible under the rules implementing PHS Act section 2704 for issuers in the individual market to screen certain applicants for eligibility for alternative coverage before issuing a child-only policy. Specifically, States expressed an interest in permitting such screenings. In response to these concerns, the Departments issued Affordable Care Act Implementation FAQs Part V, Q6, which provided that under certain circumstances, States can permit issuers in the individual market to screen applicants for eligibility for alternative coverage options before offering a child-only policy if (1) the practice is permitted under State law; (2) the screening applies to all child-only applicants, regardless of health status; and (3) the alternative coverage options include options for which healthy children would potentially be

³⁵ See 45 CFR 147.102, 154.101 *et seq.*, and 156.80.

eligible, such as the Children's Health Insurance Program (CHIP) and group health insurance.³⁶ Screenings may not be limited to programs targeted to individuals with a preexisting condition, such as a State high risk pool. Note that Medicaid policy, under 42 U.S.C. 1396a (25)(G), prohibits participating States from allowing health insurance issuers to consider whether an individual is eligible for, or is provided medical assistance under, Medicaid in making enrollment decisions. Furthermore, issuers may not implement a screening process that by its operation significantly delays enrollment or artificially engineers eligibility of a child for a program targeted to individuals with a preexisting condition. Additionally, the screening process may not be applied to offers of dependent coverage for children. The FAQ provided that States are encouraged to require issuers that screen for other coverage to enroll and provide coverage to the applicant effective on the first date that the child-only policy would have been effective had the applicant not been screened for an alternative coverage option. It also provided that States are encouraged to impose a reasonable time limit, such as 30 days, at which time the issuer would have to enroll the child regardless of pending applications for other coverage. Subsequent to the issuance of the FAQ, the guaranteed availability requirements in section 2702 of the PHS Act took effect, similarly precluding an issuer from denying coverage. This screening, as permitted under State law, will continue to be allowed under these final regulations, consistent with both section 2704 and guaranteed availability obligations under section 2702.

C. PHS Act Section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815-2711, 29 CFR 2590.715-2711, 45 CFR 147.126)

PHS Act section 2711, as added by the Affordable Care Act, generally prohibits annual and lifetime dollar limits on essential health benefits, as defined in section 1302(b) of the Affordable Care Act. With respect to annual dollar limits, PHS Act section 2711(a)(2) provided that for plan years beginning before January 1, 2014, restricted annual dollar limits were allowed. On June 28, 2010, the Departments issued interim final regulations implementing PHS Act

³⁶ See Affordable Care Act Implementation FAQs Part V, available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.

section 2711 and requested comment.³⁷ After issuance of the 2010 interim final regulations, the Departments also released Affordable Care Act Implementation FAQs Parts IV, XI, XV, XXII, as well as Technical Release 2013–03, to address various requests for clarifications under PHS Act section 2711.³⁸ These final regulations adopt the 2010 interim final regulations without substantial change and incorporate certain pertinent clarifications issued thus far in subregulatory guidance.

1. Definition of Essential Health Benefits

On February 25, 2013, HHS issued final regulations addressing essential health benefits (EHB) under Affordable Care Act section 1302.³⁹ Among other things, HHS regulations defined EHB based on a State-specific benchmark plan and required each State to select a benchmark plan from among several options.⁴⁰ While self-insured, large group market, and grandfathered health plans are not required to offer EHB, PHS Act section 2711 prohibits such plans from imposing annual and lifetime dollar limits on covered benefits that fall within the definition of EHB. In the interim final regulations, the Departments said that “[f]or plan years (in the individual market, policy years) beginning before the issuance of regulations defining ‘essential health benefits,’ for purposes of enforcement, the Departments will take into account good faith efforts to comply with a

reasonable interpretation of the term ‘essential health benefits.’”

In a 2012 FAQ, HHS stated that the Departments would consider a self-insured group health plan, a large group market health plan, or a grandfathered group health plan to have used a permissible definition of EHB under section 1302(b) of the Affordable Care Act if the definition was one of the potential EHB base-benchmark plans that, at the time, States could have chosen from as the standard for EHB in their State.⁴¹ At the time, this list of potential EHB-benchmark plans included over 510 EHB base-benchmark plans that were authorized by the Secretary for a State or the District of Columbia⁴² to select, as each State and the District of Columbia has a choice of ten possible benchmark plans. All of these potential plans were “authorized” in the sense that they were potential EHB benchmark plans that could be selected by a State or the District of Columbia under the EHB regulations. This approach was intended to provide plans and issuers not subject to the EHB rules with flexibility to define what constitutes EHB under their respective plan for purposes of the limits in PHS Act section 2711. Since that time, each State and the District of Columbia has selected or defaulted to a single EHB-benchmark option, and that is the only benchmark plan “authorized” to be used for defining EHB in that State or the District of Columbia.

Given the enforcement challenges for Federal and State regulators and difficulties for participants, beneficiaries, and enrollees in ascertaining what benefits under their respective plans constitute EHB posed by a choice of over 500 plans, the Departments are codifying their interpretation that a “reasonable interpretation of the term ‘essential health benefits’” includes only those EHB base-benchmarks that, in fact, have been selected, whether by active State selection or by default to be the EHB base-benchmark plan for a State, rather than all plans that are potentially authorized.

In addition to the foregoing base-benchmark plans, there are three base-benchmark plan options not currently among those a State or the District of Columbia has either selected or had assigned by default that the Departments believe should also continue to be made available for plans and issuers not subject to EHB requirements. These three plan options are the current base-benchmark plan options under the Federal Employees Health Benefit Program (FEHBP) specified at 45 CFR 156.100(a)(3) (the three largest FEHBP plans available to all Federal employees nationally). These base-benchmark plan options are unique among base-benchmark plans in that they are available nationally, and thus can be utilized to determine what benefits would be categorized as EHBs for those employers who provide health coverage to employees throughout the United States and are not situated only in a single State.

Thus, under these final regulations, group health plans (and health insurance coverage offered in connection with such plans) and grandfathered individual market coverage that are not required to provide EHB may select among any of the 51 EHB base-benchmark plans identified under 45 CFR 156.100 and selected by a State or the District of Columbia and the FEHBP base-benchmark plan, as applicable for plan years beginning on or after January 1, 2017, for purposes of determining which benefits cannot be subject to annual and lifetime dollar limits. The current list of the 51 proposed EHB base-benchmark plans selected by the States for 2017 can be found at <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html>. HHS anticipates publishing the final list later this month.

2. Out-of-Network Benefits

The Departments have been asked whether the scope of the prohibition on lifetime and annual dollar limits in PHS Act section 2711 applies only to in-network benefits as opposed to both in-network and out-of-network benefits. The statute and interim final regulations made no distinction between in-network or out-of-network benefits. Therefore, lifetime and annual dollar limits on essential health benefits are generally prohibited, regardless of whether such benefits are provided on an in-network or out-of-network basis. These final regulations incorporate this clarification.

3. End of Waiver Program

Under PHS Act section 2711, for plan years beginning before January 1, 2014,

³⁷ 75 FR 37188 (June 28, 2010).

³⁸ Affordable Care Act Implementation FAQs Parts IV, XI, XV, XXII, available at <http://www.dol.gov/ebsa/faqs/faq-aca4.html>, <http://www.dol.gov/ebsa/faqs/faq-aca11.html>, <http://www.dol.gov/ebsa/faqs/faq-aca15.html>, and <http://www.dol.gov/ebsa/faqs/faq-aca22.html>, or https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs11.html, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXII-FINAL.pdf>; Technical Release 2013–03, available at <http://www.dol.gov/ebsa/newsroom/tr13-03.html>. See footnote 51 for a list of additional items of guidance under PHS Act section 2711.

³⁹ 78 FR 12834.

⁴⁰ The benchmark plans from which a State could choose are: (1) The largest plan by enrollment in any of the three largest products in the State’s small group market; (2) any of the largest three State employee health benefit plans options by enrollment; (3) any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by enrollment; or (4) the largest insured commercial HMO in the State. 45 CFR 156.100. The EHB-benchmark plan serves as a reference plan, reflecting both the scope of services and limits offered by a typical employer plan in each State. The term “base-benchmark plan” in 45 CFR 156.100 is distinct from the term “EHB-benchmark plan” as defined in 45 CFR 156.20.

⁴¹ See Q10 of Frequently Asked Questions on Essential Health Benefits Bulletin, available at <https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf>.

⁴² Initially, issuers in the territories were subject to the EHB requirement and also had potential benchmarks to choose from under the EHB regulations. A change in the interpretation of the statute resulted in issuers in the territories being exempt from the EHB rules. See Letter to Gary R. Francis, Commissioner, Office of Lieutenant Governor, Virgin Islands, dated July 16, 2014, available at <https://www.cms.gov/CCIIO/Resources/Letters/Downloads/letter-to-Francis.pdf>.

the Departments were given authority to define restricted annual dollar limits to ensure that access to needed services was made available with minimal impact on premiums. As noted in the preamble to the 2010 interim final regulations, in order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to EHB, the interim final regulations adopted a three-year phased approach for restricted annual dollar limits, with the dollar limit increasing for each year of the three year period. Annual dollar limits, including restricted annual dollar limits, are not allowed for plan years (in the individual market, policy years) beginning on or after January 1, 2014, except for grandfathered individual health insurance coverage.

Some previously widely available low-cost coverage was designed with low maximum benefits and did not meet the phased in restricted annual dollar limits, such as stand-alone health reimbursement arrangements (HRAs)⁴³ and so-called “mini med” plans. In order to ensure that individuals with such limited coverage would not be denied access to needed services or experience more than a minimal impact on premiums, the interim final regulations also provided for HHS to establish a program under which the restricted annual dollar limit requirements would be waived if compliance with the limits would result in a significant decrease in access to benefits or a significant increase in premiums.⁴⁴ However, this waiver program was only available for the period during which the statute authorized restricted annual dollar limits, that is, plan years (in the individual market, policy years) beginning before January 1, 2014. Consequently such waivers are no longer available and the waiver program

⁴³ An HRA is an arrangement that is funded solely by an employer and that reimburses an employee for medical care expenses (as defined under Code section 213(d)) incurred by the employee, or his spouse, dependents, and any children who, as of the end of the taxable year, have not attained age 27, up to a maximum dollar amount for a coverage period. IRS Notice 2002–45, 2002–02 CB 93; Revenue Ruling 2002–41, 2002–2 CB 75. This reimbursement is excludable from the employee’s income. Amounts that remain at the end of the year generally can be used to reimburse expenses incurred in later years. HRAs generally are considered to be group health plans within the meaning of Code section 9832(a), section 733(a) of ERISA, and section 2791(a) of the PHS Act and are subject to the rules applicable to group health plans.

⁴⁴ Guidance regarding the annual dollar limit waiver program was issued at <https://www.cms.gov/ccio/resources/Regulations-and-Guidance/index.html#AnnualLimits>.

rules are not incorporated in these final regulations.

4. HRAs and Other Account Based Plans

In general, HRAs and other account-based group health plans are subject to the annual dollar limit prohibition under PHS Act section 2711 (annual dollar limit prohibition)⁴⁵ and will fail to comply with this prohibition because these arrangements impose an annual limit on the amount of expenses the arrangement will reimburse. However, special rules apply to certain types of account-based plans under which the HRA or other account-based health plan either is not subject to the annual dollar limit prohibition, or is considered to comply with the annual dollar limit prohibition if it is “integrated” with another group health plan that complies with the annual dollar limit prohibition.

The preamble to the interim final regulations noted that the annual dollar limit prohibition applies differently to certain account-based plans that are subject to other rules that limit the benefits available under those plans.⁴⁶ In particular, under the 2010 interim final regulations and these final regulations, certain health Flexible Spending Arrangements (health FSAs)⁴⁷ are not subject to the PHS Act section 2711 annual dollar limit prohibition because health FSAs are subject to specific limits under section 9005 of the Affordable Care Act. In addition, as noted in the preamble to the 2010 interim final regulations, the annual dollar limit prohibition does not apply to Archer Medical Savings Accounts (Archer MSAs) under section 220 of the Code and Health Savings Accounts (HSAs) under section 223 of the Code, because both types of plans

⁴⁵ In accordance with Code section 9831(a)(2) and ERISA section 732(a), the market reforms, including PHS Act section 2711, do not apply to a group health plan that has fewer than two participants who are current employees on the first day of the plan year, and, in accordance with Code section 9831(b), ERISA section 732(b), and PHS Act sections 2722(b) and 2763, the market reforms, including PHS Act section 2711, also do not apply to a group health plan in relation to its provision of excepted benefits described in Code section 9832(c), ERISA section 733(c) and PHS Act section 2791(c).

⁴⁶ See 75 FR 37188, 37190 (June 28, 2010).

⁴⁷ In general, a health FSA is a benefit designed to reimburse employees for medical care expenses (as defined in Code section 213(d), other than premiums) incurred by the employee, or the employee’s spouse, dependents, and any children who, as of the end of the taxable year, have not attained age 27. See Employee Benefits—Cafeteria Plans, 72 FR 43938, 43957 (August 6, 2007) (proposed regulations; to be codified, in part, once final, at 26 CFR 1.125–5); Code section 105(b) and 106(c). Contributions to a health FSA offered through a cafeteria plan satisfying the requirements of Code section 125 do not result in gross income to the employee. Code section 125(a).

are subject to specific statutory provisions that require that the contributions be limited.

These final regulations contain a clarification regarding the application of the annual dollar limit prohibition to health FSAs. Question and Answer 8 of DOL Technical Release 2013–03⁴⁸ and IRS Notice 2013–54⁴⁹ clarified that the annual dollar limit prohibition applies to a health FSA that is not offered through a Code section 125 plan. That is because the exemption for health FSAs from the annual dollar limit prohibition is intended to apply only to health FSAs that are subject to the separate annual limitation under Code section 125(i), and health FSAs that are not offered through a Code section 125 plan are not subject to that separate statutory limit. The prior guidance provided that this clarification was intended to apply beginning September 13, 2013 and the guidance noted that the Departments intended to amend the annual dollar limit prohibition regulations to conform to the Q&A. These final regulations include this amendment.

Other types of account-based plans, such as HRAs and employer payment plans,⁵⁰ are not exempt from the annual dollar limit prohibition. However, the preamble to the interim final regulations and subsequently issued subregulatory guidance⁵¹ interpreting these rules included a number of rules regarding the application of the annual dollar limit prohibition to these types of arrangements. In particular, this guidance provides that if an HRA is “integrated” with other group health

⁴⁸ Technical Release 2013–03, available at www.dol.gov/ebsa/pdf/tr13-03.pdf.

⁴⁹ 2013–40 IRB 287.

⁵⁰ An employer payment plan is a group health plan under which an employer reimburses an employee for some or all of the premium expenses incurred for an individual health insurance policy, such as a reimbursement arrangement described in Revenue Ruling 61–146, 1961–2 CB 25, or arrangements under which the employer uses its funds to directly pay the premium for an individual health insurance policy covering the employee.

⁵¹ Five items of guidance have been issued on this topic: (1) Affordable Care Act Implementation FAQs Part XI, available at (<http://www.dol.gov/ebsa/faqs/faq-aca11.html>) or http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca-implementation_faqs11.html; (2) IRS Notice 2013–54 and DOL Technical Release 2013–03, issued on September 13, 2013; (3) IRS FAQ on Employer Healthcare Arrangements available at <http://www.irs.gov/Affordable-Care-Act/Employer-Health-Care-Arrangements>; (4) Affordable Care Act Implementation FAQs Part XXII, available at <http://www.dol.gov/ebsa/faqs/faq-aca22.html> or <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXII-FINAL.pdf>; and (5) IRS Notice 2015–17, issued on February 18, 2015. See also 75 FR 37188 (June 28, 2010). This guidance, much of which is not directly addressed in these final regulations, continues to be in effect.

plan coverage, and the other group health plan coverage complies with the requirements of PHS Act section 2711, the combined arrangement satisfies the requirements even though the HRA imposes a dollar limit.⁵² The basic principles for when an HRA is considered integrated with other group health plan coverage have been set forth in various forms of subregulatory guidance and have been included in these final regulations.

These final regulations clarify the scope of arrangements, in addition to HRAs, that can be integrated with other group health plan coverage by defining and referring to “account-based plans.” Account-based plans are employer-provided group health plans that provide reimbursements of medical expenses other than individual market policy premiums, with the reimbursement subject to a maximum fixed dollar amount for a period. Examples of account-based plans include health FSAs and medical reimbursement plans that are not HRAs, in addition to HRAs. Account-based plans that do not qualify as excepted benefits⁵³ generally are subject to the market reforms (except that health FSAs offered through a Code section 125 plan are not subject to the annual dollar limit prohibition), including the preventive services requirements under PHS Act section 2713. If the other group health plan coverage with which an account-based plan is integrated complies with the requirements under PHS Act

⁵² Issues also arise for account-based group health plans under PHS Act section 2713, which requires non-grandfathered group health plans (or health insurance issuers offering group health insurance plans) to provide certain preventive services without imposing any cost-sharing requirements for these services. The Departments have issued guidance providing that, similar to the analysis of the annual dollar limit prohibition, an HRA that is integrated with a group health plan will comply with the preventive services requirements if the group health plan with which the HRA is integrated complies with the preventive services requirements. Also, a group health plan, including an HRA, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of the preventive services requirements and therefore will fail to comply with the preventive services requirements because an HRA or similar arrangement does not provide preventive services without cost-sharing in all instances. See DOL Technical Release 2013–03 and IRS Notice 2013–54.

⁵³ Health FSAs will be considered to provide only excepted benefits if the employer also makes available group health plan coverage that is not limited to excepted benefits and the health FSA is structured so that the maximum benefit payable to any participant cannot exceed two times the participant’s salary reduction election for the health FSA for the year (or, if greater, cannot exceed \$500 plus the amount of the participant’s salary reduction election). See 26 CFR 54.9831–1(c)(3)(v), 29 CFR 2590.732(c)(3)(v), and 45 CFR 146.145(c)(3)(v).

sections 2711 and 2713, the account-based plan also complies with those requirements because, in that case, the combined benefit satisfies those requirements.⁵⁴

The Departments’ prior guidance regarding when an HRA is considered integrated with another group health plan provides two methods for integration, each of which has been added to the final regulations and extended to other account-based plans. In addition to various other requirements, each integration method requires that under the terms of the HRA or other account-based plan, (1) an employee (or former employee) must be permitted to permanently opt out of and waive future reimbursements from the account-based plan at least annually, and (2) upon termination of employment either remaining funds are forfeited or the employee is allowed to opt out of and waive future reimbursements under the account-based plan.

Stakeholders have requested clarification regarding whether for this purpose a forfeiture of amounts or a waiver of reimbursements under an HRA includes an otherwise permanent forfeiture or waiver, if the amounts will be reinstated or the waiver will be discontinued upon a fixed date or death. The Departments interpret the prior guidance to provide, and the final regulations clarify, that forfeiture or waiver occurs even if the forfeited amounts or waived reimbursements may be reinstated upon a fixed date, a participant’s death, or the earlier of the two events (the reinstatement event). For this purpose, an HRA 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, the participant and the participant’s beneficiaries have no access to amounts credited to the HRA until the reinstatement event.⁵⁵ This means that the HRA may not be used to reimburse or pay medical expenses incurred

⁵⁴ See Affordable Care Act Implementation FAQs Part XIX, available at <http://www.dol.gov/ebsa/faqs/fq-aca19.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html.

⁵⁵ During a period in which an HRA has been forfeited or waived prior to a reinstatement event, the participant is considered not covered by the HRA. For a former employee (such as a retiree), an individual’s right to have a forfeited or waived HRA reinstated upon a reinstatement event will not prevent the individual from receiving the premium tax credit under § 36B during the period after forfeiture or waiver and prior to reinstatement, if the individual is otherwise eligible for a premium tax credit. See 26 CFR 1.36B–2(c)(3)(f), proposed § 1.36B–2(c)(3)(iv).

during the period after the forfeiture or waiver and prior to reinstatement. An HRA need not provide for reinstatement of forfeited amounts or waived reimbursements to be integrated with a non-HRA group health plan. The final regulations reflect this clarification, and this clarification applies for integration of HRAs as well as other account-based plans, as defined in the regulations.

The Departments’ prior guidance regarding integration of an HRA or other account-based plan with another group health plan further provides that integration requires, among other requirements, that the plan sponsor offering the HRA or other account-based plan also offer to the employee another group health plan (other than the HRA or other account-based plan). On February 18, 2015, Treasury and IRS issued Notice 2015–17, which, in Q&A3, provided for integration of a premium reimbursement arrangement for an employee’s Medicare part B or D premiums for purposes of the annual dollar limit prohibition and the preventive services requirements under PHS Act section 2713 if the arrangement meets certain conditions and the employer offers the employee another group health plan.⁵⁶ However, Notice 2015–17 provided that the premium reimbursement arrangement for an employee’s Medicare part B or D premiums could not be integrated with Medicare coverage to satisfy the market reforms because Medicare coverage is not a group health plan. In response to this prior guidance, stakeholders have indicated that employers with fewer than 20 employees are unable to meet the integration test set out in Notice 2015–17 for Medicare part B or D premium reimbursement arrangements. That is because these employers that offer group health plan coverage are not required by the applicable Medicare secondary payer rules to offer group health plan coverage to their employees who are eligible for Medicare coverage, and some issuers of insurance for group health plans do not allow these smaller employers to offer group health plan coverage to their employees who are eligible for Medicare coverage. In response to these concerns, these regulations now provide a special rule for employers with fewer than 20 employees that are not required to offer their group health plan coverage to employees who are eligible for Medicare

⁵⁶ Notice 2015–17 provides special rules for integration of Medicare Part B and D premium reimbursement arrangements and TRICARE-related HRAs with other group health plans, along with various other related pieces of guidance. That guidance continues to apply but is not repeated in these final regulations.

coverage, and that offer group health plan coverage to their employees who are not eligible for Medicare, but not to their employees who are eligible for Medicare coverage. For these employers, a premium reimbursement arrangement for Medicare part B or D premiums may be integrated with Medicare (and deemed to satisfy) the annual dollar limit prohibition and the preventive services requirements under PHS Act section 2713 if the employees who are not offered the other group health plan coverage would be eligible for that group health plan but for their eligibility for Medicare. These employers may use either of the non-Medicare specific integration tests, as applicable, for account-based plans for employees who are not eligible for Medicare.

Although in certain circumstances HRAs and other account-based plans may be integrated with another group health plan to satisfy the annual dollar limit prohibition, these final regulations incorporate the general rule set forth in prior subregulatory guidance clarifying that an HRA and other account-based plans may not be integrated with individual market coverage, and therefore an HRA or other account-based plan used to reimburse premiums for the individual market coverage fails to comply with PHS Act section 2711.

These final regulations, however, do not incorporate all of the other subregulatory guidance concerning the application of the Affordable Care Act to HRAs and other account-based plans. It has come to the Departments' attention that there are a wide variety of account-based products being marketed, often with subtle but insubstantial differences, in an attempt to circumvent the guidance set forth by the Departments on the application of the annual dollar limit prohibition and the preventive services requirements to account-based plans. The Departments intend to continue to address these specific instances of noncompliance. The subregulatory guidance not specifically addressed in these final regulations continues to apply and the Departments will continue to address additional situations as necessary.

D. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815-2712, 29 CFR 2590.715-2712, 45 CFR 147.128)

PHS Act section 2712, as added by the Affordable Care Act, provides that a group health plan or health insurance issuer offering group or individual health insurance coverage must not rescind coverage unless a covered individual commits fraud or makes an intentional misrepresentation of material fact. This standard applies to

all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer. On June 28, 2010, the Departments issued interim final regulations implementing PHS Act section 2712.⁵⁷ The interim final regulations included several clarifications regarding the standards for rescission, including that the rules of PHS Act section 2712 apply whether the coverage is rescinded for an individual or a group. The Departments also issued Affordable Care Act Implementation FAQs Part II Q7, which clarified when retroactive terminations in the 'normal course of business' would not be considered rescissions.⁵⁸ These final regulations finalize the 2010 interim final regulations without substantial change and incorporate the clarifications issued thus far in subregulatory guidance.

1. Definition of Rescission

Under the interim final regulations and these final regulations, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats an insurance policy as void from the time of an individual's or group's enrollment is a rescission, whether the cancellation is a result of the issuer subsequently determining that a valid insurance contract does not exist or the insurance contract was entered into despite its noncompliance with applicable law. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission. However, a cancellation or discontinuance of coverage is not a rescission if it has only prospective effect or to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage. Other provisions of Federal and State law limit the grounds for prospective cancellations of coverage, including PHS Act section 2703 regarding guaranteed renewability of coverage and PHS Act section 2705 regarding non-discrimination in rules for eligibility (or continued eligibility) based on health status.

Under PHS Act section 2712, rescission is not prohibited if a covered individual commits fraud or makes an intentional misrepresentation of material fact. Some commenters recommended that the Departments

define the term "material fact." These final regulations decline this suggestion. However, the Departments have addressed whether providing false or inaccurate information concerning tobacco use is considered a misrepresentation of material fact for this purpose. HHS published final regulations under PHS Act section 2701 (regarding fair health insurance premiums) on February 13, 2013.⁵⁹ In the preamble to those regulations, HHS stated that, with respect to an individual who is found to have reported false or inaccurate information about their tobacco use, the individual may be charged the appropriate premium that should have been paid retroactive to the beginning of the plan year. However, as stated in the preamble, the "remedy of recoupment renders any misrepresentation with regard to tobacco use no longer a 'material' fact for purposes of rescission under PHS Act section 2712 and its implementing regulations," and therefore, coverage cannot be rescinded on such basis. The Departments may provide further guidance regarding the definition of a "material fact" for purposes of rescission under PHS Act section 2712 if additional questions arise.

2. Scope and Application

The statutory prohibition related to rescissions is not limited to rescissions based on prior medical history, rather it precludes plans and issuers from rescinding coverage under any circumstances except as provided in the statute and regulations. For example, coverage cannot be rescinded because an individual makes a mistake on an insurance application or enrollment form. An example in both the interim final regulations and in these final regulations clarifies that some plan errors (such as mistakenly covering a part-time employee for a period of time under a plan that only covers full-time employees) may be cancelled prospectively once identified, but not retroactively rescinded unless there was fraud or intentional misrepresentation of a material fact by the employee.

The Departments received comments on the interim final regulations stating that some employers' human resource departments may reconcile lists of eligible individuals with their plan or issuer via data feed only once per month, and that routine enrollment adjustments in the normal course of business should not be considered a rescission.

In response to these comments, the Departments issued an FAQ concerning

⁵⁷ 75 FR 37188 (June 28, 2010).

⁵⁸ Affordable Care Act Implementation FAQs Part II, available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> or https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

⁵⁹ 78 FR 13406, 13414 (February 13, 2013).

rescissions on October 8, 2010.⁶⁰ The FAQ stated that if a plan covers only active employees (subject to the COBRA continuation of coverage provisions) and an employee pays no premiums for coverage after termination of employment, the Departments do not consider the retroactive elimination of coverage back to the date of termination of employment, due to delay in administrative record-keeping, to be a rescission. Similarly, if a plan does not cover ex-spouses and the plan is not notified of a divorce (subject to the COBRA continuation coverage provisions), and the full COBRA premium is not paid by the employee or ex-spouse for coverage, the Departments do not consider a plan's termination of coverage retroactive to the divorce to be a rescission.⁶¹

3. Termination of Coverage Initiated by Participant, Beneficiary, or Enrollee

The Departments have been asked whether the rescission rules prohibit a plan or issuer from retroactively terminating coverage at the request of a participant, beneficiary, or enrollee. In the Departments' view, the statutory provision was enacted by Congress to protect individuals against potential abuses by group health plans and health insurance issuers; it was not intended to prevent individuals from exercising their rights and privileges under the terms of the plan or coverage in accordance with applicable State law, where they are acting voluntarily and without coercion by the plan or issuer. Moreover, HHS regulations at 45 CFR 155.430, which govern termination of enrollment in the Exchange, permit enrollees and the Exchange to initiate a retroactive termination of enrollment in a QHP through the Exchange, including instances where the enrollee has the right to terminate coverage under applicable State law (such as State "free look" cancellations laws).⁶² For these reasons, the Departments clarify in these final regulations that a retroactive cancellation or discontinuance of coverage is not a rescission if (1) it is initiated by the individual (or by the individual's authorized representative) and the employer, sponsor, 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 (2) it is initiated by the Exchange pursuant to 45 CFR 155.430 (other than under paragraph (b)(2)(iii)). The Departments may issue additional subregulatory guidance if abusive situations or questions arise.

4. Interaction With Internal Appeals and External Review

Commenters requested that these final regulations provide that individuals have the right to appeal a rescission to an independent third party. PHS Act section 2719 and its implementing regulations address internal claims and appeals and external review of adverse benefit determinations. Under the Department of Labor's claims procedure regulation at 29 CFR 2560.503-1 (the DOL claims procedure regulation), adverse benefit determinations eligible for internal claims and appeals processes generally include denial, reduction, termination of, or a failure to provide or make a payment (in whole or in part) for a benefit, including a denial, reduction, termination, or failure to make a payment based on the imposition of a preexisting condition exclusion, a source of injury exclusion, or other limitation on covered benefits. The Departments' regulations under PHS Act section 2719 broaden the definition of "adverse benefit determination" to include rescissions of coverage. Therefore, rescissions of coverage are also eligible for internal claims and appeals and external review for non-grandfathered health plans, whether or not the rescission has an adverse effect on any particular benefit at the time of an appeal. The regulations under PHS Act section 2719 also contain provisions requiring coverage to remain effective pending the outcome of an internal appeal.

5. Interaction With COBRA Continuation Coverage

COBRA provides for a temporary continuation of group health coverage that would otherwise be lost due to certain life events. COBRA requires group health plans to offer continuation coverage to covered employees, former employees, spouses, former spouses, and dependent children when group health coverage would be terminated due to the following: The death of a covered employee; termination or reduction in the hours of a covered employee's employment for reasons other than gross misconduct; a covered

employee's becoming entitled to Medicare; divorce or legal separation of a covered employee and spouse; and a child's loss of dependent status (and therefore coverage) under the plan.

COBRA sets forth rules for how and when continuation coverage must be offered and provided, how employees and their families may elect continuation coverage, and what circumstances justify terminating continuation coverage. COBRA allows plans to continue coverage during an initial 60-day election period and allows plans to continue providing coverage during the 30-day grace periods for each premium payment. If a qualified beneficiary fails to pay for coverage during the initial election period, or fails to pay in full before the end of a grace period, continuation coverage may be terminated retroactively under COBRA.

Several commenters sought clarification about the interaction of the COBRA continuation provisions with the prohibition against rescissions. The Departments clarify that the regulatory exception to the prohibition on rescission for failure to timely pay required premiums or contributions toward the cost of coverage also includes failure to timely pay required premiums towards the cost of COBRA continuation coverage. Accordingly, if a group health plan requires the payment of a COBRA premium to continue coverage after a qualifying event and that premium is not paid by the applicable deadline, the prohibition on rescission is not violated if the plan retroactively terminates coverage due to a failure to elect and pay for COBRA continuation coverage.

6. Notice of Rescission

Consistent with PHS Act section 2712, under the interim final regulations and these final regulations, a plan or issuer must provide at least 30 calendar days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded (where permitted). This provides individuals time to appeal the decision or enroll into new coverage. This notice is required regardless of whether it is a rescission of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

Some commenters recommended the 30-day notice of rescission be coordinated with the rules for providing notices of adverse benefit determinations under the Departments'

⁶⁰ Affordable Care Act Implementation FAQs Part II, Q7 at <http://www.dol.gov/ebsa/pdf/faq-aca2.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.

⁶¹ In such situations, COBRA may require coverage to be offered for up to 36 months if the COBRA applicable premium is paid by the qualified beneficiary.

⁶² State "free look" cancellation laws are laws permitting an individual to cancel coverage within a certain time period, even following the effectuation of the enrollment.

internal appeals and external review regulations under PHS Act section 2719. Other commenters made specific suggestions regarding the content of the notice, such as that the notice indicate the basis for the rescission and include an explanation of the remedies available to the individual.

Under PHS Act section 2719, the interim final regulations, and these final regulations, a plan or issuer must provide notice to individuals, in a culturally and linguistically appropriate manner, of the reason or reasons for an adverse benefit determination or final internal adverse benefit determination (including a rescission of coverage) and a description of available internal appeals and external review processes, including information on how to initiate an appeal. The Departments encourage plans and issuers to coordinate notices related to rescissions and appeal procedures to the extent possible.

E. PHS Act Section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120)

PHS Act section 2714, as added by the Affordable Care Act, provides that a group health plan or a health insurance issuer offering group or individual health insurance coverage that makes available dependent coverage⁶³ of children must make such coverage available for children until attainment of 26 years of age.⁶⁴ On May 13, 2010, the Departments issued interim final regulations implementing PHS Act section 2714 and requesting comment.⁶⁵ After issuance of the 2010 interim final regulations, the Departments released Affordable Care Act Implementation FAQs Parts I and V to address various requests for clarifications under PHS Act section 2714.⁶⁶ These final

⁶³ For purposes of these final regulations, dependent coverage means coverage of any individual under the terms of a group health plan, or group or individual health insurance coverage, because of the relationship to a participant (in the individual market, primary subscriber).

⁶⁴ Under section 1004(d) of the Reconciliation Act and IRS Notice 2010–38, 2010–20 IRB 682, released on April 27, 2010, employers may exclude from the employee's income the value of any employer-provided health coverage for an employee's child for the entire taxable year the child turns 26 if the coverage continues until the end of that taxable year. This means that if a child turns 26 in March, but stays on the plan past December 31st (the end of most individual's taxable year), the health benefits up to December 31st can be excluded from the employee's income.

⁶⁵ See 75 FR 27122 (May 13, 2010).

⁶⁶ Affordable Care Act Implementation FAQs Part I, Q&A–14, available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html and Affordable Care Act Implementation FAQs Part 5 and Mental Health

regulations adopt the 2010 interim final regulations without substantial change and incorporate the clarifications issued thus far in subregulatory guidance.

1. Restrictions on Plan Definition of Dependent

a. Definition of Dependent—Based on Relationship Between Child and Participant

PHS Act section 2714 provides that the “Secretary shall promulgate regulations to define the dependents to which coverage shall be made available” under the dependent coverage provision. The 2010 interim final regulations provided that 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. For example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the child's financial dependency (upon the participant or any other person), residency with the participant or with any other person, student status, employment, or any combination of those factors. Additional examples of factors that cannot be used for defining dependent for purposes of eligibility (or continued eligibility) include eligibility for other coverage⁶⁷ and marital status of a dependent child.⁶⁸ Because the statute does not distinguish between coverage for minor children and coverage for adult children under age 26, these factors also may not be used to determine eligibility for dependent coverage of minor children.

It has come to the Departments' attention that certain plans that utilize an HMO design impose restrictions on eligibility that require participants and beneficiaries to work, live or reside in the HMO service area. While these

Parity Implementation, Q&A 5, available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html. <http://www.dol.gov/ebsa/faqs/faq-aca5.html>.

⁶⁷ See section II.H.1. of this preamble, entitled “Special Rule Relating to Dependent Coverage of Children to Age 26 for Grandfathered Group Health Plans,” for discussion of an out-of-date special rule for grandfathered plans regarding adult children eligible for other coverage.

⁶⁸ The Affordable Care Act, as originally enacted, required plans and issuers to make dependent coverage available only to a child “who is not married.” This language was struck by section 2301(b) of the Reconciliation Act. Accordingly, under the interim final regulations and these final regulations, plans and issuers may not limit dependent coverage of children based on whether a child is married (however, a plan or issuer is not required under the final regulations to cover the spouse of an eligible child).

provisions on their face appear to be generally applicable, the overwhelming impact of such provisions affects dependent children, who would otherwise be required to be covered pursuant to PHS Act section 2714. For example, a plan that utilizes an HMO design that requires participants and beneficiaries to work, live or reside in the service area would not permit a dependent child covered under the parent's plan to continue to be eligible for the plan if the dependent child moves out of the HMO's service area to attend college. Under the same plan, however, most employees and their spouses would work, live or reside in the service area.

These final regulations provide that, to the extent such restrictions are applicable to dependent children up to age 26, eligibility restrictions under a plan or coverage that require individuals to work, live or reside in a service area violate PHS Act section 2714. (This rule does not relate to the extent to which a plan must cover participants or provide services outside of its service area). While eligibility provisions of general applicability are usually outside the scope of PHS Act section 2714, due to the disproportionate effect on dependent children, these final regulations do not permit eligibility provisions under a plan or coverage based on service area, to the extent such restrictions are applicable to dependent children up to age 26, even if such restrictions are intended to apply generally to all participants and beneficiaries under the plan.

b. Definition of Child

PHS Act section 2714 does not require a plan to provide dependent coverage of children but instead provides that if a plan does provide dependent coverage of children it must continue to make such coverage available until the child turns age 26.⁶⁹ Neither PHS Act section

⁶⁹ In general, under section 4980H of the Code, certain employers (applicable large employers) must either offer health coverage to their full-time employees (and their dependents) or potentially pay an assessable payment if at least one full-time employee receives a premium tax credit for purchasing individual coverage on an Affordable Insurance Exchange. For purposes of section 4980H, the term dependent means “a child (as defined in section 152(f)(1) of the Code but excluding a stepson, stepdaughter or an eligible foster child (and excluding any individual who is excluded from the definition of dependent under section 152 of the Code by operation of section 152(b)(3) of the Code) of an employee who has not attained age 26. A child attains age 26 on the 26th anniversary of the date the child was born. A child is a dependent for purposes of section 4980H for the entire calendar month during which he or she attains age 26. Absent knowledge to the contrary, applicable

2714 nor the interim final regulations defined the term child for purpose of the dependent coverage provision.⁷⁰

In response to comments requesting guidance on the definition of the term child and questions from stakeholders, the Departments released an FAQ⁷¹ stating that a group health plan or issuer will not fail to satisfy the dependent coverage provision merely because it conditions health coverage on support, residency, or other dependency factors for individuals under age 26 who are not described in section 152(f)(1) of the Code. For an individual not described in section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for health coverage, such as a condition that the individual be a dependent for income tax purposes. The FAQ also provided that a plan or issuer does not fail to satisfy the requirements of PHS Act section 2714 or its implementing regulations because the plan limits health coverage for children until the child turns 26 to only those children who are described in section 152(f)(1) of the Code. These final regulations incorporate the clarifications provided in the FAQ.

Some commenters requested that the Departments interpret PHS Act section 2714 to apply to grandchildren. The statute and the 2010 interim final regulations provided that nothing in PHS Act section 2714 requires a plan or issuer to make available coverage for a child of a child receiving dependent coverage. Because the statute specifically provides that plans and issuers are not required to make coverage available to grandchildren, these final regulations do not adopt this suggestion.

2. Uniformity Irrespective of Age

The 2010 interim final regulations provided that the terms of the plan or health insurance coverage providing dependent coverage of children cannot

large employer members may rely on an employee's representation about that employee's children and the ages of those children. The term dependent does not include the spouse of an employee." See 26 CFR 54.4980H-1(a)(12). Under section 152(f)(1) of the Code a child means an individual who is (i) a son, daughter, stepson, or stepdaughter of the taxpayer (including a legally adopted child or an individual lawfully placed for adoption with the taxpayer) or (ii) an eligible foster child of the taxpayer.

⁷⁰ Under section 1004(d) of the Reconciliation Act and IRS Notice 2010-38, child means child as defined in section 152(f)(1) of the Code.

⁷¹ Affordable Care Act Implementation FAQs Part I, Q&A 14 (released on September 20, 2010), available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.

vary based on the age of a child, except for children age 26 or older. The 2010 interim final regulations contained examples illustrating that age-based surcharges violate the uniformity requirement but that cost of coverage increases for tiers with more covered individuals do not violate this requirement because such an increase applies without regard to the age of any child. The 2010 interim final regulations also contained an example demonstrating that a plan that limits the benefit packages offered based on the age of dependent children violates the uniformity requirement. These final regulations retain these examples.

Following the 2010 interim final regulations, the Departments issued an FAQ⁷² that addressed an arrangement under which a group health plan charges a copayment for physician visits that do not constitute preventive services to individuals age 19 and over, including employees, spouses, and dependent children, but waives the copayment for children under age 19. The FAQ clarifies that the Departments do not consider such an arrangement to violate the dependent coverage provision. This arrangement is permissible under the dependent coverage provision because, while the dependent coverage provision prohibits distinctions based upon age in dependent coverage of children under age 26, 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 situation, the copayments charged to dependent children are the same as those charged to employees and spouses. (However, with respect to individual and small group plans required to provide essential health benefits, distinctions based on age may be considered discriminatory under HHS regulations regarding essential health benefits.⁷³) The final regulations reflect the clarification contained in this FAQ.

F. PHS Act Section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815-2719, 29 CFR 2590.715-2719, 45 CFR 147.136)

PHS Act section 2719, as added by the Affordable Care Act, applies to group health plans that are not grandfathered health plans and health insurance

⁷² Affordable Care Act Implementation Part V and Mental Health Parity Implementation FAQs, Q&A 5 (released on December 22, 2010), available at <http://www.dol.gov/ebsa/faqs/faq-aca5.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.

⁷³ See 45 CFR 156.125.

issuers offering non-grandfathered coverage in the group and individual markets, and sets forth standards for plans and issuers regarding both internal claims and appeals and external review. With respect to internal claims and appeals processes for group health plans and health insurance issuers offering group health insurance coverage, PHS Act section 2719 provides that a non-grandfathered group health plan or health insurance issuer offering non-grandfathered group coverage must initially incorporate the internal claims and appeals processes set forth in regulations promulgated by the Department of Labor (DOL) at 29 CFR 2560.503-1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor. Similarly, with respect to internal claims and appeals processes for individual health insurance coverage, issuers must initially incorporate the internal claims and appeals processes set forth in applicable State law and update such processes in accordance with standards established by the Secretary of HHS. With respect to external review, PHS Act section 2719 provides for either a State external review process or a Federal external review process.

The following list identifies certain regulations and subregulatory guidance that the Departments have issued to implement these requirements:

- Interim final regulations on July 23, 2010, at 75 FR 43329, implementing the internal claims and appeals and external review process requirements of PHS Act section 2719;
- Technical Release 2010-01, on August 23, 2010, setting forth interim procedures for Federal External Review;
- Technical Guidance, on August 26, 2010, setting forth interim procedures for Federal External Review for health insurance issuers in the group and individual markets under the Patient Protection and Affordable Care Act;
- Affordable Care Act Implementation FAQs part I, on September 20, 2010, providing guidance on outstanding questions regarding the internal claims and appeals and external review process requirements of PHS Act section 2719;
- Technical Release 2010-02, on September 20, 2010, establishing an enforcement grace period with respect to some of the internal claims and appeals standards set forth in the interim final regulations;
- Technical Release 2011-01, on March 18, 2011, extending the enforcement grace period set forth in Technical Release 2010-02;

- Technical Release 2011–02, on June 22, 2011, setting forth interim standards for a State-administered external review process authorized under section 2719(b)(2) of the PHS Act and paragraph (d) of the interim final regulations;

- Amendments to the interim final regulations on June 24, 2011, at 76 FR 37207, with respect to the internal claims and appeals and external review provisions of PHS Act section 2719 in response to comments received regarding the interim final regulations; and

- Technical Release 2013–01, on March 15, 2013, extending the interim standards for a State-administered external review process authorized under section 2719(b)(2) of the PHS Act and paragraph (d) of the interim final regulations set forth in Technical Release 2011–02.

After consideration of the comments and feedback received from stakeholders, the Departments are publishing these final regulations. These final regulations adopt the interim final regulations, as previously amended, without substantial change. These final regulations also codify some of the enforcement safe harbors, transition relief, and clarifications set forth through subregulatory guidance. Contemporaneous with the issuance of these final regulations, the Department of Labor is issuing a proposed regulation to amend the DOL claims procedure regulations under 29 CFR 2560.503–1, as applied to plans providing disability benefits. The amendment would revise and strengthen the current DOL claims procedure regulations regarding claims and appeals applicable to plans providing disability benefits primarily by adopting the protections and standards for internal claims and appeals applicable to group health plans under PHS Act section 2719 and these final regulations.

1. Internal Claims and Appeals

In addition to the requirement in PHS Act section 2719(a) that plans and issuers must initially incorporate the internal claims and appeals processes set forth in the DOL claims procedure regulation, the interim final regulations, as amended, provide further standards for compliance with the internal claims and appeals requirements of PHS Act 2719.⁷⁴ Specifically, under these

⁷⁴ The statute requires the Secretary of Health and Human Services to set forth processes for internal claims and appeals in the individual market. Under the interim final regulations, the Secretary of Health and Human Services has determined that a health insurance issuer offering individual health insurance coverage must generally comply with all the requirements for the internal claims and appeals

requirements, in addition to complying with the internal claims and appeals processes set forth in the DOL claims procedure regulation, plans and issuers are required to comply with the following standards: (1) The scope of adverse benefit determinations eligible for internal claims and appeals includes a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at the time); (2) A plan or issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a claim involving urgent care as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim by the plan or issuer; (3) Clarifications with respect to full and fair review, such that plans and issuers are clearly required to provide the claimant (free of charge) with new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan or issuer in connection with the claim, as well as any new or additional rationale for a denial at the internal appeals stage, and a reasonable opportunity for the claimant to respond to such new evidence or rationale; (4) Clarifications regarding conflicts of interest, such that decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to an individual, such as a claims adjudicator or medical expert, must not be based upon the likelihood that the individual will support the denial of benefits; (5) Notices must be provided in a culturally and linguistically appropriate manner, as required by the statute, and as set forth in paragraph (e) of the interim final regulations, as amended; (6) Notices to claimants must provide additional content, including that any notice of adverse benefit determination or final internal adverse benefit determination must include information sufficient to identify the claim involved, including the date of the 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; and (7) With the exception of de minimis violations under specified circumstances, if a plan or issuer fails to adhere to all the requirements of the interim final regulations, as amended, the claimant is deemed to have exhausted the plan's or issuer's internal claims and appeals process, and the

process that apply to group health coverage. Also, see 45 CFR 147.136 for additional requirements for coverage in the individual market.

claimant may initiate any available external review process or remedies available under ERISA or under State law.

To address certain relevant differences in the group and individual markets the interim final regulations, as amended, provided that health insurance issuers offering individual coverage must comply with three additional requirements for internal claims and appeals processes. First, initial eligibility determinations in the individual market must be included within the scope of claims eligible for internal appeals. Second, health insurance issuers offering individual coverage are only permitted to have one level of internal appeal. Third, health insurance issuers offering individual coverage must maintain records of all claims and notices associated with the internal claims and appeals process for six years. The issuer must make such records available for examination by the claimant or State, or Federal oversight agency upon request.

These final regulations generally incorporate the standards of the interim final regulations, as amended, and the Departments' associated guidance, without major change.

a. Full and Fair Review

The interim final regulations provided that plans and issuers must provide the claimant (free of charge) with new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan or issuer in connection with the claim, as well as any new or additional rationale as soon as possible and sufficiently in advance of the date on which the notice of the final adverse benefit determination is required to be provided under the DOL claims procedure regulations. Since the issuance of the interim final regulations and subsequent subregulatory guidance, stakeholders have requested additional clarification regarding how to provide a full and fair review in accordance with the requirements set forth in the regulations.

Commenters requested additional guidance related to the timing and amount of information required to be provided in order to satisfy this requirement. Specifically, individuals asked whether such information actually must be provided automatically to participants and whether or not it would be sufficient to send participants a notice informing them of the availability of new or additional evidence or rationale. The Departments retain the requirement that plans and issuers provide the new or additional evidence or rationale automatically. In

the Departments' view, fundamental fairness requires that participants and beneficiaries have an opportunity to rebut or respond to any new or additional evidence upon which a plan or issuer may rely. Therefore, plans and issuers that wish to rely on any new or additional evidence or rationale in making a benefit determination must send such new or additional evidence or rationale to participants as soon as it becomes available to the plan or issuer.

In order to comply with this requirement, a plan or issuer must send the new or additional evidence or rationale to the participant. Merely sending a notice informing participants of the availability of such information fails to satisfy this requirement. To address the narrow circumstance raised by some comments that the new or additional information could be first received so late that it would be impossible to provide it, these final regulations provide that 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 or issuer must notify the claimant of the benefit determination as soon as a plan or issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

2. Culturally and Linguistically Appropriate Standard (CLAS)

PHS Act section 2719 requires group health plans and health insurance issuers to provide relevant notices in a culturally and linguistically appropriate manner. The interim final regulations, as amended, set forth a requirement to provide notices in a non-English language if at least a specified percentage of residents in a county are literate only in the same non-English language. Specifically, with respect to group health plans and health insurance issuers offering group or individual health insurance coverage, the interim final regulations established that the threshold percentage of people who are literate only in the same non-English language is set at ten percent or more of the population residing in the claimant's county, as determined in guidance based on American Community Survey data published by the United States Census Bureau. Furthermore, the interim final

regulations, as amended, required that each notice sent by a plan or issuer to an address in a county that meets this threshold include a one-sentence statement in the relevant non-English language about the availability of language services. In addition, under the interim final regulations, as amended, plans and issuers must provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request.

In response to the culturally and linguistically appropriate standards (CLAS) set forth in the amendments to the interim final regulations described in the prior paragraph, the Departments received many comments from various stakeholders. Some commenters requested that the Departments incorporate the prior proposed CLAS (rather than the amended CLAS) into these final regulations, citing that the prior standard was less costly for plans and issuers than was stated in the proposed regulations. Other commenters requested that the threshold percentage that triggers the CLAS requirements be reduced to a lower percentage to capture a greater number of counties. Other stakeholders supported the CLAS requirements as set forth in the amendments to the interim final regulations. Stakeholders that support the amended CLAS reiterated prior comments that the Departments received that opposed the "tagging and tracking" requirement.⁷⁵

In light of all the comments received, these final regulations retain the CLAS requirements as set forth in the amendment to the interim final regulations. The Departments believe that the CLAS requirements appropriately balance the objective of protecting consumers by providing understandable notices to individuals who speak primary languages other than English with the goal of imposing reasonable language access requirements on plans and issuers. Furthermore, the Departments note that nothing in these regulations should be construed as limiting an individual's rights under Federal or State civil rights statutes, such as section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964 (Title VI) which prohibits covered entities, including issuers participating in Medicare

⁷⁵ Under the interim final regulations, the CLAS standard included a "tagging and tracking requirement" which required plans and issuers, to the extent individuals request a document in a non-English language, to "tag" and "track" such request so that any future notices would be provided automatically in the non-English language.

Advantage, from discriminating on the basis of race, color, or national origin. To ensure non-discrimination on the basis of national origin under Title VI, recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by limited English proficient persons. (For more information, see, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at <http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html>.)

3. Extension of the Transition Period for State External Review Processes

PHS Act section 2719(b) requires that a non-grandfathered group health plan that is not a self-insured plan that is not subject to State insurance regulations and a health insurance issuer offering non-grandfathered group or individual health insurance coverage comply with an applicable State external review process if that process includes, at a minimum, the consumer protections set forth in the Uniform Health Carrier External Review Model Act issued by the National Association of Insurance Commissioners (the NAIC Uniform Model Act). Paragraph (c)(2) of the 2010 interim final regulations under PHS Act section 2719, as amended, sets forth the minimum consumer protection standards that a State external review process must include to qualify as an applicable State external review process under PHS Act section 2719(b)(1) (NAIC-parallel external review process).

Under PHS Act section 2719(b)(2), if a State's external review process does not meet the minimum consumer protection standards set forth in the NAIC Uniform Model Act (or if a plan is self-insured and not subject to State insurance regulation), group health plans and health insurance issuers in the group and individual markets in that State are required to implement an effective external review process that meets minimum standards established by the Secretary of HHS through guidance. These standards must be similar to the standards established under PHS Act section 2719(b)(1) and must meet the requirements set forth in paragraph (d) of the 2010 interim final regulations, as amended.

In June 2011, the Departments amended the July 2010 interim final regulations and announced that plans and issuers could continue to participate in a State external review process that met Federal standards that were NAIC-similar for a limited time (the NAIC-similar external review

process), in anticipation that such an allowance would reduce market disruption during a transition period. Contemporaneous with the June 2011 amendment, the Departments issued guidance which, among other things, established the NAIC-similar external review process.

The Departments recognize that many States have done considerable work to bring their external review laws and processes into compliance with the NAIC Uniform Model Act and, because of those efforts, the Departments have extended the transition periods to allow States more time to meet the NAIC-parallel external review process standards. States continue to make changes to their laws through what have often proven to be complex and time consuming processes, often involving legislative changes; and it is apparent that more time is needed for some States to achieve NAIC-parallel external review processes. Therefore, the Departments are extending the NAIC-similar external review process transition period so that the last day of the transition period is December 31, 2017. Through December 31, 2017, an applicable 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), if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act. During this transition period, the NAIC-similar external review process will continue to apply⁷⁶ for non-grandfathered group health plans and issuers of non-grandfathered group or individual coverage in the State.⁷⁷ This modification seeks to minimize cost and confusion for participants and enrollees, issuers, and plans alike. Furthermore, the extension will provide States that are currently in the process of making changes to external review laws time to implement NAIC-parallel external review processes. The Departments will continue to work with health insurance issuers, States, and other stakeholders to assist them in coming into compliance

with the law. Once this transition period has ended, plans and issuers in a State that has not implemented the NAIC-parallel external review process will be required to comply with a Federal external review process.

4. Federal External Review

PHS Act section 2719(b)(2) provides that plans and issuers in States without an external review process that meets the requirements of PHS Act section 2719(b)(1) or that are self-insured plans not subject to State insurance regulation shall implement an effective external review process that meets minimum standards established by the Secretary of HHS through guidance and that is similar to a State external review process described in PHS Act section 2719(b)(1). The interim final regulations reiterated this statutory requirement, and also provided additional standards, including that the Federal external review process, like the State external review process, will provide for expedited external review and additional consumer protections with respect to external review for claims involving experimental or investigational treatment. The interim final regulations also set forth the scope of claims eligible for review under the Federal external review process. The interim final regulations also established the procedural standards that apply to claimants, plans, and issuers under this Federal external review process, as well as the substantive standards under this process. These final regulations incorporate both the procedural and substantive standards established in the interim final regulations and subsequent subregulatory guidance without substantial change and with minor clarifications.

a. Scope of Federal External Review Process

The 2010 interim final regulations set forth the original scope of claims eligible for external review under the Federal external review process. Specifically, any adverse benefit determination (including final internal adverse benefit determination) could be reviewed unless it related to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan (for example, worker classification and similar issues were not within the scope of the Federal external review process). After considering comments received in response to the 2010 interim final regulations, the Departments suspended the original rule and temporarily narrowed its scope. The amended scope

limited the Federal external review process to claims that involve (1) medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and (2) a rescission of coverage (whether or not the rescission has any effect on any particular benefit at the time). The amendments also provided two examples of claims involving medical judgment.

The Departments received mixed comments in response to the revised scope of Federal external review in the 2011 amendment to the July 2010 interim final regulations. Generally, comments supported narrowing the scope to decisions based on medical judgment and suggested permanently adopting the standards in the 2011 amendment. However, there were also commenters that objected to limiting the scope and favored the original scope as stated in the July 2010 interim final regulations. Some of these commenters stated that the description of medical judgment was ambiguous and that it was unclear how to determine whether a claim involved "medical judgment." Other commenters disagreed with the description of medical judgment, finding either the explanation was too vague or that certain information in the examples did not fall within what was normally considered medical judgment.

Additionally, the Departments received comments requesting more clarity around the treatment of coding issues under the amended scope of Federal external review. The Departments recognize that there may be instances when a patient may have a procedure performed that is similar to another and a coding issue impacts whether coverage is provided. For example, a patient may need a stoma revision, and recent significant weight loss necessitates a procedure to remove the patient's excess skin and tissue prior to addressing the stoma. However, the skin removal procedure may be coded as a cosmetic surgery, such as an abdominoplasty or "tummy tuck", instead of as a panniculectomy, and is therefore not covered. In this case both procedures involve the removal of skin from the abdomen, but one procedure is an excluded cosmetic surgery while the other is covered so long as certain medical criteria are met. This dispute would likely be resolved via an internal appeal, but in the event that the initial decision to deny coverage was affirmed on an internal appeal, the claimant

⁷⁶ If a State enacts an NAIC-parallel law prior to January 1, 2018, coverage subject to that State law will be required to comply with the provisions of that State law, in accordance with ERISA section 731 and PHS Act section 2719 and 2724.

⁷⁷ See Technical Release 2011-02, Guidance on External Review for Group Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage, and Guidance for States on State External Review Processes, June 22, 2011. The temporary standards were extended in March 15, 2013 in Technical Release 2013-01, Extension of the Transition Period for the Temporary NAIC-Similar State External Review Process under the Affordable Care Act.

could have the claim reviewed in a Federal external review process. Medical judgment is necessary to determine whether the correct code was used in the patient's case. To the extent that a coding error such as this one involves medical judgment, the claim is within the scope of Federal external review under the July 2010 interim final regulations, as amended.

After consideration of comments, these final regulations make permanent the scope for Federal external review as set out in the 2011 amendments to the July 2010 interim final regulations, to include only an adverse benefit determination that involves medical judgment as determined by the external reviewer, or a rescission of coverage. The interim final regulations included a non-exhaustive list of adverse benefit determinations that involve medical judgment. The final regulations add two items to the list of adverse benefit determinations that involve medical judgment: (1) A plan's or issuer's determination of whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program, and (2) a plan's or issuer's determination of whether a plan is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act and its implementing regulations, which generally require, among other things, parity in the application of medical management techniques. Both of these clarifications were included in preambles to regulations issued previously by the Departments.⁷⁸

b. Federal External Review Process for Self-Insured Group Health Plans

The preamble to the 2010 interim final regulations stated that the Departments will address in sub-regulatory guidance how non-grandfathered self-insured group health plans may comply with the requirements of the new Federal external review process. The Department of Labor issued Technical Releases 2010-01 and 2011-02 regarding procedures for Federal external review.⁷⁹ The technical releases set forth these procedures for non-grandfathered self-insured group health plans not subject to a State external review process. Technical Release 2011-02 also provided non-

grandfathered health insurance issuers subject to a Federally-administered external review process⁸⁰ and all non-grandfathered self-insured, non-Federal governmental plans with the option of using the external review process set out in Technical Release 2010-01.

In general, under these procedures, a group health plan must first allow a claimant to file a request for Federal external review with the plan. The group health plan must then complete a preliminary review of the request within five business days following the date of receipt of the external review request. Within one business day after completion of the preliminary review, the plan 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 (toll free number 866-444-EBSA (3272)). Upon its determination that a request is eligible for external review, the group health plan must then assign an independent review organization (IRO), accredited by URAC or by a similar nationally-recognized accrediting organization, to conduct the external review. The IRO must timely notify the claimant in writing of the external review and provide the claimant 10 business days to submit additional information that the IRO must consider. The group health plan must provide the IRO with any documents and information used in making the original determination within five business days after the date of the assignment and the IRO must forward any information submitted by the claimant to the group health plan within one business day after receipt of the information. The IRO must review all information and documents timely received and must provide written notice of the final external review decision to the claimant and the group health plan within 45 days after the request for the external review. After the final external review decision, the IRO must maintain records of all associated claims and notices for six years. If the IRO has decided to reverse the original determination, then, upon receipt of the IRO's notice of this decision, the group health plan must

immediately provide coverage or payment for the claim.

The technical releases also provided that a group health plan must allow a claimant to make a request for expedited external review for benefit determinations involving a medical condition for which the timeframe for completion of an expedited internal appeal or standard external review under the interim final regulations would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function. The IRO must provide a notice of the final external review decision 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 expedited 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.

These final regulations incorporate the guidance in Technical Releases 2010-01 and 2011-02 without substantial change. These final regulations also continue to permit non-grandfathered self-insured plans to comply with the external review process outlined in these final regulations or a State external review process if the State chooses to expand access to their State external review process to plans that are not subject to the applicable State laws.

Furthermore, these final regulations continue to provide issuers subject to a Federally-administered external review process and all self-insured, non-Federal governmental plans with the option of electing the private accredited IRO process for external review described in these final regulations or the Federally-administered external review process, which is administered by HHS (also referred to as the HHS-administered external review process).

Similar to the technical releases, these final regulations continue to provide that group health plans must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. Moreover, the plan must take action to protect against bias and to ensure independence. Accordingly, plans must contract with at least three IROs for assignments under the plan and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection). In addition, the IRO may not be eligible for any financial incentives based on the likelihood that the IRO

⁷⁸ See 78 FR 33158, 33164 (June 3, 2013); see also 78 FR 68240, 68247-8 (November 13, 2013).

⁷⁹ See Technical Release 2010-01, available at: <http://www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf> and Technical Release 2011-02, available at: <http://www.dol.gov/ebsa/pdf/tr11-02.pdf>.

⁸⁰ Where a State's external review process does not meet the Federal consumer protection standards, issuers and self-insured non-Federal governmental plans may choose to utilize either the Federal IRO external review process or an HHS-administered Federal external review process in which a designated Federal contractor will perform all functions of the external review.

will support the denial of benefits. (Of course, plans also may not terminate an IRO's contract in retaliation for granting claims.) For issuers and all self-insured, non-Federal governmental plans participating in the HHS-administered external review process, the requirement to take action to protect against bias and to ensure independence is satisfied without contracting with three IROs for assignment and rotating the claims assignments among them. Under the HHS-administered external review process, there are other unique factors that ensure independence and the absence of bias such as HHS oversight and lack of privity of contract between the issuer or self-insured non-Federal governmental plan and the IRO.

After issuance of the interim final regulations and technical releases, the Departments received questions relating to self-insured group health plans contracting directly with IROs. While such a group health plan must designate an IRO to conduct any external review, neither the interim final regulations nor the technical releases require a plan to contract directly with any IRO. As clarified in the FAQs about the Affordable Care Act implementation, issued on September 20, 2010, where a self-insured plan contracts with a third party administrator that, in turn, contracts with an IRO, the standards of the technical release can be satisfied in the same manner as if the plan had contracted directly. Such a contract does not automatically relieve the plan from responsibility if there is a failure to provide an individual with external review and fiduciaries of plans that are subject to ERISA have a duty to monitor the service providers to the plan. Furthermore, plans may contract with an IRO in another State, as these final regulations do not require the plan to be located in the same State as the IRO. If additional questions arise regarding the IRO external review process, the Departments may issue additional subregulatory guidance.

c. Filing Fees for External Review

The Departments also received comments related to the standard allowing consumers to be charged a filing fee when requesting external review. While the original 2004 NAIC model upon which the 2010 interim final regulations was based expressly permitted imposition of a nominal filing fee for a claimant requesting an external review, and a small number of States have adopted this approach, the 2010 NAIC model did not address this topic. Commenters on the 2010 interim final regulations indicated that the ability to charge a filing fee should be prohibited

because such fees may dissuade consumers from filing an appeal, even in cases where the fee is not a financial hardship for the consumer.

The Departments find the change in the NAIC model to be important and are concerned that any fee may impose a financial hardship on some claimants or discourage them from seeking external review. Therefore, these final regulations generally prohibit the imposition of filing fees for external review on claimants. However, the Departments recognize that several States' external review processes currently applicable to group and individual coverage permit nominal filing fees. Therefore, in determining whether a State external review process provides the claimants with minimum consumer protections, these final regulations do not invalidate existing State external review processes because they permit a nominal filing fee, consistent with the 2004 NAIC model.⁸¹ Therefore, plans and coverage subject to such laws may continue to impose nominal fees for as long as such laws continue to apply. For this purpose, consistent with the interim final regulations, to be considered nominal, the filing fee must not exceed \$25, must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, 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. All other plans and coverage must pay the full cost of the IRO for conducting the external review, without imposing any nominal filing fee.

G. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138)

PHS Act section 2719A, as added by the Affordable Care Act provides, with respect to a non-grandfathered group health plan or health insurance issuer offering non-grandfathered group or individual health insurance coverage, rules regarding the designation of primary care providers, if a plan or issuer requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider. In addition, the statute provides requirements relating to benefits for emergency services. On June 28, 2010,

⁸¹ Twelve States expressly authorize nominal fees: Connecticut, Hawaii, Kentucky, Massachusetts, Minnesota, New Jersey, New York, North Dakota, Rhode Island, South Dakota, Vermont, and Wyoming.

the Departments issued interim final regulations implementing PHS Act section 2719A.⁸² The Departments also released Affordable Care Act Implementation FAQs Part I Q15 to address an issue with respect to emergency services.⁸³ These regulations adopt the 2010 interim final regulations without substantial change and incorporate the clarification issued in subregulatory guidance.

1. Choice of Healthcare Professional

The interim final regulations and these final regulations state that if a plan or issuer requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any primary care provider who is available to accept the participant, beneficiary, or enrollee and who participates in the network of the plan or issuer.

Commenters recommended clarifying that in instances where a participant, beneficiary, or enrollee is incapacitated, a family member may select the primary care provider on their behalf. Under existing State and Federal law, including ERISA, a duly authorized representative is permitted to act on behalf of a participant or beneficiary for all purposes, including the designation of a primary care provider as provided under these final regulations. The final regulations regarding the designation of a primary care provider do not include any new text to address cases of incapacity. However, as with all of the market reform provisions, a duly authorized representative may act on behalf of a participant or beneficiary to the extent permitted under other applicable Federal and State law.

Commenters recommended that participants, beneficiaries, and enrollees be allowed to designate a provider of any specialty or licensure as their primary care provider to improve access to care. For example, commenters recommended that enrollees have the option of designating a nurse practitioner as their primary care provider. The Departments do not define primary care provider for purposes of these final regulations. The classification of who is considered a primary care provider is determined under the terms of the plan or coverage

⁸² 75 FR 37188 (June 28, 2010).

⁸³ Affordable Care Act Implementation FAQs Part I, Q&A–15, available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca-implementation_faqs.html.

and in accordance with applicable State law.

If a plan or issuer 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 designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusion with respect to coverage of pediatric care.

Some commenters recommended that participants, beneficiaries, or enrollees have the option to designate physicians of various pediatric sub-specialties as the child's primary care provider to improve access to specialty care without prior authorization from a primary care coordinator. For example, commenters suggested that a pediatric cancer patient with a serious chronic condition should have the option of designating a pediatric oncologist that can provide cancer treatment as well as other routine treatment as the child's primary care provider. The Departments interpret this provision to mean that if a plan or issuer 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 designation of any physician (allopathic or osteopathic) who specializes in pediatrics, including pediatric subspecialties, based on the scope of that provider's license under applicable State law. The designated provider must also participate in the plan network and be available to accept the child. These final regulations incorporate this clarification.

The interim final regulations also established requirements for a plan or issuer that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. Specifically, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. Plans and issuers must also treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the

authorization of the primary care provider. For this purpose, a health care professional specializing in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

Commenters sought clarification that women of all ages may receive obstetrical and gynecological care without prior authorization or referral by the plan, issuer, or any person (including a primary care provider), noting that the statutory provision contains no restrictions based on the age of a participant, beneficiary or enrollee. The Departments agree that all women regardless of age are ensured direct access to obstetrical and gynecological care under this provision.

Since the promulgation of the interim final regulations, it has come to the Departments' attention that some plans and issuers utilize plan designs where the delivery of care is coordinated through medical groups within the network based on the geographic location of the participant and the provider. Specifically, the Departments have encountered plan provisions in insured group health plan coverage that require participants to designate a primary care provider but restrict a participant's choice of provider based on the distance that the participant lives or works from the provider. Stakeholders requested that the Departments clarify in the final regulations that the choice of healthcare professional provision does not prohibit the application of such geographical limitations with respect to the selection of primary care providers. Stakeholders highlighted that prohibiting such geographical limitations would fundamentally disrupt these plan designs, as well as the underlying negotiated capitation arrangements (where payment is rendered on a per person rather than per service basis). Stakeholders also noted that the underlying provider contracts do not permit providers to accept participants that are not within the specified geographic limit, and, accordingly, such limitations should not violate these provisions of the regulations, as the providers are not available to accept such participants, based on the terms of the plan, and as required by the regulations.

The Departments recognize the importance of allowing plans and issuers the flexibility to deliver care in a cost-effective and efficient manner. Accordingly, these final regulations include a codification of the Departments' interpretation that plans and issuers are not prohibited under

PHS Act section 2719A from applying reasonable and appropriate geographic limitations with respect to which participating primary care providers are considered available for purposes of selection as primary care providers, in accordance with the terms of the plan, the underlying provider contracts, and applicable State law. The Departments may provide additional guidance if questions persist or if the Departments become aware of geographic limitations that unduly restrict a participant's choice of provider.

2. Emergency Services

a. Additional Administrative Requirements

Under the interim final regulations and these final regulations, if a group health plan or issuer provides any benefits with respect to services in the emergency department of a hospital, then the plan or issuer must provide coverage for emergency services without the individual or the health care provider having to obtain prior authorization (even if the emergency services are provided out of network). For a plan or health insurance coverage with a network of providers that provide benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services.

b. Out-of-Network Cost-Sharing Requirements

Cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. The preamble to the interim final regulations explained that out-of-network providers may bill patients for the difference between the providers' billed charges and the amount collected from the plan or issuer and the amount collected from the patient in the form of a copayment or coinsurance amount (referred to as balance billing⁸⁴). Section 1302(c)(3)(B) of the Affordable Care Act excludes such balance billing amounts from the definition of cost sharing, and the requirement in section 2719A(b)(1)(C)(ii)(II) that cost sharing for out-of-network services be limited to that imposed in network only applies to

⁸⁴ See Uniform Glossary of Health Coverage and Medical Terms at <http://www.dol.gov/ebsa/pdf/sbcuniforglossaryproposed.pdf> and <https://www.cms.gov/apps/glossary>.

cost sharing expressed as a copayment amount or coinsurance rate. Because the statute neither requires plans or issuers to cover balance billing amounts, nor prohibits balance billing, even where the protections in the statute apply, patients may still be subject to balance billing. In the preamble to the interim final regulations under PHS Act section 2719A, the Departments explained that it would defeat the purpose of the protections in the statute if a plan or issuer paid an unreasonably low amount to a provider, even while limiting the coinsurance or copayment associated with that amount to in-network amounts.⁸⁵

To avoid the circumvention of the protections of PHS Act section 2719A, the Departments determined it necessary that a reasonable amount be paid before a patient becomes responsible for a balance billing amount. Therefore, as provided in the interim final regulations and these final regulations, a plan or issuer must pay a reasonable amount for emergency services by some objective standard. Specifically, a plan or issuer satisfies the copayment or coinsurance limitations in the statute if it provides benefits for out-of-network emergency services (prior to imposing in-network cost sharing) in an amount at least equal the greatest of: (1) The median amount negotiated with in-network providers for the emergency service; (2) 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); or (3) the amount that would be paid under Medicare for the emergency service (minimum payment standards). The interim final regulations under PHS Act section 2719 clarified that the cost-sharing requirements create a minimum payment requirement. The cost-sharing requirements do not prohibit a group health plan or health insurance from providing benefits with respect to an emergency service that are greater than the amounts specified in the regulations.

Some commenters expressed concern about the level of payment for out-of-network emergency services and urged the Departments to require plans and issuers to use a transparent database to determine out-of-network amounts. The Departments believe that this concern is addressed by our requirement that the amount be the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C)

of this section (which are adjusted for in-network cost-sharing requirements).

c. Clarifications Regarding Balance Billing

Some commenters sought clarification about the interaction of the minimum payment standards under the interim final regulations and State laws that prohibit balance billing for emergency services. Balance billing generally is the practice of billing by a provider that is not a preferred provider for the difference between the charge of a provider that is not a preferred provider and the allowed amount under the plan or coverage. Some stakeholders expressed their opposition to the use of balance billing because it creates a substantial financial burden and may discourage a participant, beneficiary, or enrollee from obtaining the care needed in an emergency situation. Other stakeholders suggested that plans and issuers should be required to negotiate contracts with hospitals and facility-based providers that avoid balance billing. However, the statute does not require plans or issuers to cover balance billed amounts, nor does it prohibit balance billing. Even where the protections in the statute apply, a participant, beneficiary, or enrollee may be subject to balance billing. In the future, the Departments will consider ways to prevent providers from billing a participant, beneficiary, or enrollee for emergency services from out-of-network providers at in-network hospitals and facilities. States may also consider ways to prevent balance billing in these circumstances.

The minimum payment standards are designed to reduce potential amounts of balance billing to patients. Stakeholders commented that in circumstances where patients will not be balance billed (because balance billing is prohibited or because the issuer, rather than the patient, is required to cover the balance bill), the minimum payment standards are not necessary. In response to these comments, the Departments issued an FAQ⁸⁶ stating that the minimum payment standards set forth in the interim final regulations were developed to protect patients from being financially penalized for obtaining emergency services on an out-of-network basis. If State law prohibits balance billing, plans and issuers are not required to satisfy the payment minimum set forth in the regulations. Similarly, if a plan or issuer is

contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, the plan or issuer is not required to satisfy the payment minimum. In both situations, however, 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. In addition, a plan or issuer must provide an enrollee or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to amounts balance billed in order to prevent inadvertent payment by an enrollee or beneficiary. These final regulations incorporate this clarification. The regulations do not preempt existing State consumer protection laws and do not prohibit States from enacting new laws with respect to balance billing that would provide consumer protections at least as strong as the Federal statute.

In response to the interim final regulations, commenters also requested that the Departments require plans and issuers to inform a participant, beneficiary, or enrollee using clear and understandable language of the consequences of using out-of-network emergency services, including the possibility of balance billing. Another commenter stated that the summary plan description (SPD) provides sufficient information to meet the notice requirements. The Departments agree that plans and issuers must disclose the terms of the coverage as part of plan documents and are not adding a new notice requirement at this time.

d. Definition of Emergency Services

In applying the rules relating to emergency services, the terms emergency medical condition, emergency services, and stabilize have the meaning given to those terms under the Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act. Under EMTALA, the term emergency services includes (1) “an appropriate medical screening examination that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department, to determine whether an emergency medical condition exists”; and (2) “such further medical examination and such treatment as may be required to stabilize the medical condition.”⁸⁷

⁸⁶ See Affordable Care Act Implementation FAQ Part I Q15 at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and https://www.cms.gov/CCHIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.

⁸⁷ 42 U.S.C. 1395dd(a)–(b).

⁸⁵ 75 FR 37188, 37194 (June 28, 2010).

Some commenters recommended that the Departments define “emergency services” such that an enrollee or beneficiary may only receive emergency benefits if an enrollee or beneficiary seeks treatment within 24 hours of the onset of an emergency. These final regulations decline to adopt this comment. The term “emergency services” as defined by the interim final regulations and these final regulations is based on the statutory definition, which does not specify parameters with respect to time. Accordingly, a plan or issuer cannot set a time limit within which to seek emergency services and must provide coverage for any emergency services that meet the definition of emergency services under EMTALA.

Some commenters requested clarification as to whether air ambulance transport and other emergency transportation is within the scope of the term “emergency services.” The Departments decline to provide a rule addressing this issue. These final regulations continue to provide that the terms emergency medical condition, emergency services, and stabilize have the meaning given to those terms under EMTALA, section 1867 of the Social Security Act.⁸⁸

H. Provisions No Longer Applicable

1. Special Rule Relating to Dependent Coverage of Children to Age 26 for Grandfathered Group Health Plans

The dependent coverage provision of PHS Act section 2714 applies to all 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 September 23, 2010, whether or not the plan or health insurance coverage qualifies as a grandfathered health plan. However, consistent with section 2714 of the PHS Act, for plan years beginning before January 1, 2014, the 2010 interim final regulations provided that a grandfathered health plan that is a group health plan that makes available dependent coverage of children may exclude from coverage an adult child who has not attained age 26 if the child is eligible to enroll in an employer-sponsored health plan (as defined in section 5000A(f)(2) of the Code) other than a group health plan of a parent. Because this special rule for

grandfathered group health plans no longer applies, it is not incorporated into these final regulations.

2. Transitional Rules for Individuals Whose Coverage Ended by Reason of Reaching a Dependent Eligibility Threshold

The 2010 interim final regulations implementing PHS Act section 2714 provided transitional relief for a child whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26. The 2010 interim final regulations also required a plan or issuer to give such a child a special enrollment opportunity, which was required to be provided (including written notice) not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. Because the transitional rule no longer applies, it is not incorporated into these final regulations.

3. Restricted Annual Limits and Transitional Rules for Individuals Whose Coverage or Benefits Ended by Reason of Reaching a Lifetime Dollar Limit

PHS Act section 2711 and its implementing interim final regulations generally prohibited lifetime or annual limits on the dollar value of EHBs (as defined in section 1302(b) of the Affordable Care Act). With respect to annual dollar limits, the statute and the interim final regulations allowed the imposition of “restricted annual limits” with respect to EHBs for plan years (in the individual market, policy years) beginning before January 1, 2014. The interim final regulations adopted a three-year phased approach to restricted annual limits. As set forth in the interim final regulations, the restricted annual limits on the dollar value of EHBs could not be lower than:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, \$750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, \$1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, \$2 million.

With respect to plan or policy years beginning on or after January 1, 2014, no annual dollar limits are permitted on essential health benefits except in the

case of grandfathered individual market coverage.

The interim final regulations also provided transitional rules for individuals who reached a lifetime dollar limit under a group health plan or health insurance coverage prior to the applicability date of the interim final regulations. The regulations required a plan or issuer to provide an individual whose coverage ended due to reaching a lifetime dollar limit with an enrollment opportunity (including written notice) that continues for at least 30 days. The notice and enrollment opportunity was required to be provided not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. Because the provisions regarding restricted annual dollar limits and the transitional rules regarding lifetime dollar limits no longer apply, they are not incorporated into these final regulations.

I. Applicability

1. General Applicability

These final regulations apply to group health plans and health insurance issuers beginning on the first day of the first plan year (or, in the individual market, the first day of the first policy year) beginning on or after January 1, 2017. Until these final regulations become applicable, plans and issuers are required to continue to comply with the corresponding interim final regulations at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015, and 45 CFR parts 144, 146, and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015. In accordance with section 7805(e)(2) of the Code, the corresponding temporary regulations promulgated by the Department of the Treasury are inapplicable. Under section 104 of the Health Insurance Portability and Accountability Act (HIPAA), enacted on August 21, 1996, and subsequent amendments, the Departments must coordinate policies with respect to parallel provisions of ERISA, the PHS Act, and the Code (shared provisions). The Departments operate under a Memorandum of Understanding⁸⁹ implementing HIPAA section 104 which provides that the shared provisions must be administered so as to have the same effect at all times and the Departments must coordinate policies relating to enforcing the shared provisions in order to avoid duplication of enforcement efforts and to assign

⁸⁸ For a more detailed discussion of definitions and requirements under EMTALA, see CMS State Operations Manual, Appendix V, pg. 33–41, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf.

⁸⁹ See 64 FR 70164 (December 15, 1999).

priorities in enforcement. Therefore, until these final regulations promulgated by the Department of the Treasury become applicable, compliance with corresponding interim final regulations at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015 shall satisfy corresponding requirements of the Code.

Section 1251 of the Affordable Care Act provides that grandfathered health plans are subject to only certain provisions of the Affordable Care Act. The final regulations under PHS Act section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, 45 CFR 147.136) and PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138) do not apply to grandfathered health plans. Final regulations under PHS Act section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108); PHS Act section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815–2711, 29 CFR 2590.715–2711, 45 CFR 147.126); PHS Act section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.128); and PHS Act section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120) apply to grandfathered health plans, except the prohibition of preexisting condition exclusions and prohibition on annual dollar limits do not apply to grandfathered health plans that are individual health insurance coverage. For a list of the market reform provisions under title XXVII of the PHS Act, as added or amended by the Affordable Care Act and incorporated into ERISA and the Code, applicable to grandfathered health plans, visit <http://www.dol.gov/ebsa/pdf/grandfatherregtable.pdf>.

2. Expatriate Plans

On December 16, 2014, Congress enacted the Expatriate Health Coverage Clarification Act of 2014 (EHCCA) as part of the Consolidated and Further Continuing Appropriations Act, 2015, Division M, Public Law 113–235. The EHCCA provides that the market reform requirements of the Affordable Care Act generally do not apply to expatriate

health plans, expatriate health insurance issuers with respect to expatriate health plans, and employers in their capacity as plan sponsors of expatriate health plans. However, the plans, coverage, sponsors and issuers must still satisfy provisions of the PHS Act, ERISA and the Code that would otherwise apply if not for the enactment of the Affordable Care Act. The EHCCA exception from the market reform requirements applies to expatriate health plans that are issued or renewed on or after July 1, 2015.

Treasury and IRS issued Notice 2015–43, 2015–29 I.R.B. 73, to provide interim guidance on the EHCCA. The notice provides that until the issuance of further guidance and except as otherwise provided in the notice, issuers, employers, and plan sponsors generally may apply the requirements of EHCCA using a reasonable good faith interpretation of the statute. The notice also provides that until further guidance is issued, using the definition of expatriate health plan provided in Affordable Care Act Implementation FAQs⁹⁰ is treated as a reasonable good faith interpretation of the statute. As explained in the notice, the Departments intend to publish proposed regulations implementing and providing guidance on the EHCCA. Consequently, these final regulations do not address the application to expatriate health plans of the Affordable Care Act provisions under which these final regulations are promulgated.

III. Economic Impact Analysis— Departments of Labor and Health and Human Services

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Under Executive Order 12866 (58 FR 51735), “significant” regulatory actions are subject to review by the Office of Management and Budget (OMB).

Section 3(f) of the Executive Order defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. These final regulations have been designated “significant regulatory actions” under section 3(f) of Executive Order 12866. Accordingly, the regulations have been reviewed by the Office of Management and Budget.

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year). The Departments have concluded that these final regulations would have economic impacts of \$100 million or more in at least one year, thus meeting the definition of an “economically significant rule” under Executive Order 12866. Therefore, consistent with Executive Orders 12866 and 13563, the Departments have provided an assessment of the potential benefits and the costs associated with these final regulations.

The Departments expect these final regulations, when compared with the interim final regulations, to have marginal benefits and costs. This is because they primarily provide clarifications of the previous interim final regulations issued in 2010 and 2011 and incorporate subregulatory guidance, including frequently asked questions and safe harbors issued by the Departments. The Departments do not have sufficient data to quantify these costs and benefits, but they are qualitatively discussed throughout the remainder of this section and summarized in the Accounting Table.

⁹⁰ See FAQs about Affordable Care Act Implementation (Part XIII), Q&A–1, available at <http://www.dol.gov/ebsa/pdf/faq-aca13.pdf> and [http://www.cms.gov/CCIIO/Resources/Fact-Sheets-](http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ACA_implementation_faqs13.html)

[and-FAQs/ACA_implementation_faqs13.html](http://www.dol.gov/ebsa/pdf/faq-and-FAQs/ACA_implementation_faqs13.html). See also FAQs about Affordable Care Act Implementation (Part XVIII), Q&A–6 and Q&A–7, available at <http://www.dol.gov/ebsa/pdf/faq->

[aca18.pdf](http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ACA_implementation_faqs18.html) and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ACA_implementation_faqs18.html.

TABLE 1—ACCOUNTING TABLE

Category	Estimate	Year dollar	Discount rate	Period covered
Benefits—Qualitative: These final regulations help ensure the protections and benefits intended by Congress. Many of these benefits have a distributional component, and promote equity, in the sense that they will benefit those who are especially vulnerable as a result of health problems and financial status. Other benefits include increased access to care and to information needed to protect consumer’s rights. These final regulations also lead to improved health outcomes for patients and increase certainty for issuers, plans and consumers by providing clarifications and guidance.				
Costs:				
Annualized Monetized	\$169.9	2015	7%	2016–2025
(\$millions/year)	\$169.9	2015	3%	2016–2025
Qualitative: The Departments have quantified where possible the costs associated with these final regulations. These costs include burden that will be incurred to prepare and distribute required disclosures and notices, and to bring plan and issuers’ policies and procedures into compliance with the new requirements. The Departments have not been able to quantify cost related to increased access to care. To the extent these patient protections increase access to health care services, increased health care utilization and costs could result.				
Transfers:				
Annualized Monetized	\$53.5	2015	7%	2016–2025
(\$millions/year)	\$53.5	2015	3%	2016–2025
Qualitative: Due to the risk pooling nature of health insurance these patient protections and other requirements create a transfer from those paying premiums to those individuals and families now obtaining increased protections, coverage and services.				

1. Need for Regulatory Action

a. Preservation of Right To Maintain Existing Coverage

Section 1251 of the Affordable Care Act provides that grandfathered health plans are subject only to certain provisions of the Affordable Care Act. The statute, however, is silent regarding changes plan sponsors and issuers can make to plans and health insurance coverage while retaining grandfather status.

These final regulations are necessary in order to provide rules that group health plans and health insurance issuers can use to determine which changes they can make to the terms of the plan or health insurance coverage while retaining their grandfather status, thus exempting them from certain provisions of the Affordable Care Act and fulfilling a goal of the legislation, which is to allow those that like their coverage to keep it. These final regulations are designed to allow individuals to keep the coverage they had on March 23, 2010 (the date of enactment of the Affordable Care Act) to reduce short term disruptions in the market, and to ease the transition required by the market reforms.

In drafting this rule, the Departments attempted to balance a number of competing interests. For example, the Departments sought to provide adequate flexibility to group health plans and issuers to ease transition and mitigate potential premium increases while avoiding excessive flexibility that would unduly delay implementation of critical consumer protections in the Affordable Care Act. In addition, the Departments

recognized that many group health plans and issuers make changes to the terms of plans or health insurance coverage on an annual basis: Premiums fluctuate, provider networks and drug formularies change, employer and employee contributions and cost-sharing change, and covered items and services may vary. Without some ability to make some adjustments while retaining grandfather status, the ability of individuals to maintain their current coverage would be frustrated, because most plans or health insurance coverage would quickly cease to be regarded as the same group health plan or health insurance coverage in existence on March 23, 2010. At the same time, allowing unfettered changes while retaining grandfather status would also be inconsistent with Congress’s intent to provide a transition to the Affordable Care Act market reforms.

These final regulations regarding grandfather health plans are designed, among other things, to take into account reasonable changes routinely made by plan sponsors or issuers without the plan or health insurance coverage relinquishing its grandfather status. Thus, for example, these final regulations generally permit plans and issuers to make voluntary changes to increase benefits, to conform to required legal changes, and to voluntarily adopt other consumer protections in the Affordable Care Act without relinquishing grandfather status.

b. Prohibition of Preexisting Condition Exclusions

Section 2704 of the PHS Act, as added by the Affordable Care Act, generally

prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing any preexisting condition exclusion.

Studies estimate that preexisting conditions affect approximately 129 million Americans⁹¹ which includes a broad range of conditions, from heart disease—affecting an estimated 85.6 million American adults (with more than 1 in 3 having one or more types of cardiovascular disease⁹²)—to cancer—which in 2012 affected an estimated 14 million Americans and will affect an estimated 1.7 million additional people in 2015⁹³—to relatively minor conditions like hay fever, asthma, or previous sports injuries.⁹⁴ Denials of benefits or coverage based on a preexisting condition previously made adequate health insurance unavailable to millions of Americans. Before enactment of the Affordable Care Act, in 45 States, health insurance issuers in the individual market could deny coverage, charge higher premiums, and/

⁹¹ ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011.

⁹² Mozzafarian, D., et al. Heart Disease and Stroke Statistics—2015 Update: A Report From the American Heart Association. *Circulation*. 2015; 131(4):e29–322.

⁹³ National Cancer Institute: Surveillance, Epidemiology, and End Results Program (SEER) Stat Fact Sheet: All Cancer Types. <http://seer.cancer.gov/statfacts/html/all.html>.

⁹⁴ Pollitz, K., et al. How Accessible is Individual Health Insurance for Consumers in Less than Perfect Health? Kaiser Family Foundation, June 2001.

or deny benefits for a preexisting condition.⁹⁵

These regulations finalize interim final regulations which were necessary to implement this statutory provision which Congress enacted to help ensure that quality health coverage is available to more Americans without the imposition of a preexisting condition exclusion.

c. Lifetime and Annual Limits

Section 2711 of the PHS Act, as added to the Affordable Care Act, generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing annual and lifetime limits on the dollar value of essential health benefits.

These protections ensure that patients are not confronted with devastating healthcare costs because they have exhausted their health coverage when faced with a serious medical condition.

These regulations finalize interim final regulations that were necessary to implement the statutory provisions with respect to annual and lifetime limits that Congress enacted to help ensure that more Americans with chronic, long-term, and/or expensive illnesses have access to quality health coverage.

d. Prohibition on Rescissions

Section 2712 of the PHS Act, as added by the Affordable Care Act, prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from rescinding coverage except in the case of fraud or intentional misrepresentation of material fact.

Prior to the Affordable Care Act, thousands of Americans lost health coverage each year due to rescission. When a coverage rescission occurs, an individual's health coverage is retroactively cancelled, which means that the insurance company is no longer responsible for medical care claims that had previously been accepted and paid. Rescissions can result in significant financial hardship for affected individuals, because, in most cases, the individuals have accumulated significant medical expenses.

These final regulations implement the statutory provision enacted by Congress to protect the most vulnerable Americans, those that incur substantial medical expenses due to a serious medical condition, from financial devastation by ensuring that such individuals do not unjustly lose health coverage by rescission.

e. Coverage of Dependents to Age 26

PHS Act section 2714, as added by the Affordable Care Act, requires group health plans and health insurance issuers offering group or individual health insurance coverage that make dependent coverage available for children to continue to make coverage available to such children until the attainment of age 26. With respect to a child receiving dependent coverage, coverage does not have to be extended to a child or children of the child or a spouse of the child. Furthermore these final regulations clarify that 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 health coverage, such as a condition that the individual be a dependent for income tax purposes, and the final regulations also clarify that distinctions based upon age that apply generally to all individuals covered under the plan (employees, spouses, dependent children) are not prohibited. These regulations finalize the interim final regulations, which were necessary to implement the statute.

f. Internal Claims and Appeals and External Review

Before the enactment of the Affordable Care Act, health plan sponsors and issuers were not uniformly required to implement claims and appeals processes. For example, ERISA-covered group health plan sponsors were required to implement internal claims and appeal processes that complied with the DOL claims procedure regulation,⁹⁶ while group health plans that were not covered by ERISA, such as plans sponsored by State and local governments were not. Health insurance issuers offering coverage in the individual insurance market were required to comply with various applicable State internal appeals laws but were not required to comply with the DOL claims procedure regulation.

With respect to external appeal processes, before the enactment of the Affordable Care Act, sponsors of fully insured ERISA-covered group health plans, fully-insured State and local governmental plans, and fully-insured church plans were required to comply with State external review laws, while self-insured ERISA-covered group health plans were not subject to such laws due to ERISA preemption. In the individual health insurance market, issuers in States with external review laws were required to comply with such

laws. However, uniform external review standards did not apply, because State external review laws vary from State-to-State. Moreover, at least six States did not have external review laws when the Affordable Care Act was enacted; therefore, prior to the Affordable Care Act, issuers in those States were not required to implement an external review process.

Under this regulatory system, inconsistent claims and appeals processes applied to plan sponsors and issuers and a patchwork of consumer protections were provided to participants, beneficiaries, and enrollees. The applicable processes and protections depended on several factors including whether (1) plans were subject to ERISA, (2) benefits were self-funded or financed by the purchase of an insurance policy, (3) issuers were subject to State internal claims and appeals laws, and (4) issuers were subject to State external review laws, and if so, the scope of such laws (such as, whether the laws only apply to one segment of the health insurance market, e.g., managed care or HMO coverage). These uneven protections created an appearance of unfairness, increased cost for issuers and plans operating in multiple States, and may have led to confusion among consumers about their rights.

Congress enacted PHS Act section 2719 to ensure that plans and issuers implemented more uniform internal and external claims and appeals processes and to set a minimum standard of consumer protections that are available to participants, beneficiaries, and enrollees. These final regulations are necessary to provide rules that plan sponsors and issuers can use to implement effective internal and external claims and appeals processes that meet the requirements of PHS Act section 2719.

These changes do not add any incremental costs to those associated with the 2010 interim final rules, because they simply incorporate sub-regulatory guidance that was already issued.

g. Patient Protections

Section 2719A of the PHS Act, as added by the Affordable Care Act, requires group health plans and health insurance issuers offering group or individual health insurance coverage to ensure choice of healthcare professionals (including pediatricians, obstetricians, and gynecologists) and greater access to benefits for emergency services. Provider choice is a strong predictor of patient trust in a provider, and patient-provider trust can increase

⁹⁵ Levitt, L., *et al.* How Buying Insurance Will Change Under Obamacare. Kaiser Family Foundation, September 2013.

⁹⁶ 29 CFR 2560.503-1.

health promotion and therapeutic effects.⁹⁷ Studies have found that patients tend to experience better quality healthcare if they have long-term relationships with their healthcare provider.⁹⁸

The emergency care provisions of PHS Act section 2719A require (1) non-grandfathered group health plans and health insurance issuers that cover emergency services to cover such services without prior authorization and without regard to whether the health care provider furnishing the services is a participating network provider, and (2) copayments and coinsurance for out-of-network emergency care do not exceed the cost-sharing requirements that would have been imposed if the services were provided in-network. These provisions will help to ensure that patients receive covered emergency care when they need it, especially in situations where prior authorization cannot be obtained due to exigent circumstances or an in-network provider is not available to provide the services. They also will protect patients from the substantial financial burden that can be imposed when differing copayment or coinsurance arrangements apply to in-network and out-of-network emergency care.

These regulations finalize the interim final regulations that were necessary to implement the statutory provision enacted by Congress to provide these essential patient protections.

A. Section 1251 of the Affordable Care Act, Preservation of Right To Maintain Existing Coverage (26 CFR 54.9815–1251, 29 CFR 2590.715–1251, 45 CFR 147.140)

1. Affected Entities and Individuals

The Departments estimate that there are 2.3 million ERISA-covered plans with an estimated 66 million policy holders and 130.2 million participants and beneficiaries in those plans.⁹⁹ Similarly, the Departments estimate that there are 128,400 State and local governmental health plans¹⁰⁰ with an

⁹⁷ Piette, John, *et al.*, “The Role of Patient-Physician Trust in Moderating Medication Nonadherence Due to Cost Pressures.” *Archives of Internal Medicine* 165, August (2005) and Roberts, Kathleen J., “Physician-Patient Relationships, Patient Satisfaction, and Antiretroviral Medication Adherence Among HIV-Infected Adults Attending a Public Health Clinic.” *AIDS Patient Care and STDs* 16.1 (2002).

⁹⁸ Blewett, Lynn, *et al.*, “When a Usual Source of Care and Usual Provider Matter: Adult Prevention and Screening Services.” *Journal of General Internal Medicine* 23.9 (2008).

⁹⁹ EBSA estimates based on the 2014 Medical Expenditure Survey—Insurance Component.

¹⁰⁰ The estimate of the total number of State and local governmental plans is based on the 2012 Census of Government.

estimated 21.1 million policy holders and 41.1 million participants and beneficiaries in those plans.¹⁰¹

The 2014 Employer Health Benefits Survey reports that 37 percent of firms offer health benefits that have at least one health plan that is a grandfathered plan, and 26 percent of employees are enrolled in grandfathered plans.¹⁰² Using the above estimates, there are 851,000 (2.3 million ERISA-covered plans * 0.37) ERISA-covered plans with 17.2 million policy holders (66 million policy holders * 0.26) and 33.9 million participants and beneficiaries (130.2 million participants and beneficiaries * 0.26). There are approximately 47,500 grandfathered State and local governmental health plans (0.37 * 128,400 plans¹⁰³) with approximately 5.5 million policyholders (21.1 million policy holders * 0.26) and 10.7 million participants and beneficiaries (41.1 million participants and beneficiaries * 0.26).

There were an estimated 1.4 million policies with grandfathered coverage during 2013 with 2.2 million enrollees.¹⁰⁴

2. Discussion of Economic Impacts of Retaining or Relinquishing Grandfather Status

The economic effects of these final regulations will depend on decisions by plan sponsors and issuers, as well as by those covered under these plans and health insurance coverage.

For a plan sponsor or issuer, the potential economic impact of the application of the provisions in the Affordable Care Act may be one consideration in making its decisions. To determine the value of retaining a health plan’s grandfather status, each plan sponsor or issuer must determine whether the rules applicable to grandfathered health plans are more or less favorable than the rules applicable to non-grandfathered health plans. This determination will depend on such factors as the respective prices of grandfathered and non-grandfathered health plans, as well as the preferences of grandfathered health plans’ covered populations and their willingness to pay

¹⁰¹ Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2014 Annual Social and Economic Supplement to the Current Population Survey, Table 3C <http://www.dol.gov/ebsa/pdf/coveragebulletin2014.pdf>.

¹⁰² Kaiser Family Foundation, “2014 Employer Health Benefits Survey.” <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/>.

¹⁰³ The estimate of the total number of State and local governmental plans is based on the 2012 Census of Government.

¹⁰⁴ Based on data from the McKinsey Center for U.S. Health System Reform and Medical Loss Ratio submissions for 2013 reporting year.

for benefits and patient protections available under non-grandfathered health plans. In making its decision whether to maintain grandfather status, a plan sponsor or issuer is also likely to consider the market segment (because different rules apply to the large and small group market segments), and the utilization pattern of its covered population. Those costs and benefits of the various provisions of the Affordable Care Act and their interaction with the coverages’ grandfathered status have been discussed in the impact analysis of those individual requirements and are not repeated here.

3. Impacts on the Individual Market

The market for individual insurance is significantly different than that for group coverage. As discussed in previous interim final regulations issued in 2010 and 2011, for many, the market is transitional, providing a bridge between other types of coverage. One study found a high percentage of individual insurance policies began and ended with employer-sponsored coverage.¹⁰⁵ More importantly, coverage on particular policies tends to be for short periods of time. As such, high turnover rates are likely the chief source of changes in grandfather status. Reliable data are scant, so there is no ability to update estimates as to how many people in the individual market are in non-grandfathered plans today.

1. Disclosure of Grandfather Status and Document Retention

To maintain grandfathered health plan status under these final regulations, a plan or issuer must maintain records that document the plan or policy terms 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, disclose its status as a grandfathered health plan, and if switching issuers and intending to maintain its status as a grandfathered plan, it must provide to the new health insurance issuer with documentation of plan terms under the prior health coverage sufficient for it to determine whether a change causing a cessation of grandfathered health plan status has occurred.

The Departments estimate that the total cost for these requirements will be \$1.8 million annually. For a detailed discussion of the grandfathered health plan document retention and disclosure requirements, see the Paperwork

¹⁰⁵ Adele M. Kirk, *The Individual Insurance Market: A Building Block for Health Care Reform? Health Care Financing Organization Research Synthesis*. May 2008.

Reduction Act section later in this preamble.

B. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108)

1. Affected Entities and Individuals

In the individual market, those applying for insurance will no longer face exclusions or denials of coverage based on a preexisting condition while those covered by non-grandfathered individual coverage with a rider or exclusion period will gain coverage for any preexisting condition otherwise covered by the plan. In the group market, participants and beneficiaries that have experienced a lapse in coverage will no longer face up to a twelve-month exclusion for preexisting conditions.

There are two main categories of people who have most likely been directly affected by this provision: First, those who had a preexisting condition and who were uninsured; second, those who were covered by grandfathered individual policies containing riders excluding coverage for a preexisting condition or have an exclusion period. It is difficult to estimate precisely how many uninsured individuals had a preexisting condition as of when this provision went into effect, as information on whether individuals have a preexisting condition for the purpose of obtaining health insurance is not collected in any major population based survey and can include conditions from hay fever to HIV/AIDS, all which could result in a denial of coverage.¹⁰⁶ The Departments find it difficult to estimate the number of individuals that will be uniquely affected by these final regulations due to the interactions with other provisions of the Affordable Care Act; however, estimates indicate that 50–129 million non-elderly individuals with a preexisting condition, 25 million uninsured individuals—including the 3.7 million adults that fall into the “coverage gap” in States without Medicaid expansion, and the estimated 66.6–82 million with ESI with preexisting conditions could benefit from these final regulations.¹⁰⁷

¹⁰⁶ Levitt, L., *et al.* How Buying Insurance Will Change Under Obamacare. *Kaiser Family Foundation*, September 2013.

¹⁰⁷ ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011 and Artiga, S. *et al.* The Impact of the Coverage Gap in States not Expanding Medicaid by Race and Ethnicity. *The Kaiser Family Foundation*, April 2015.

2. Benefits

These final regulations will expand and improve coverage for those Americans with preexisting conditions; those currently diagnosed, undiagnosed, or who will develop conditions as they age. This will likely increase access to health care, improve health outcomes, and reduce family financial strain and “job lock.”

For many years insurance providers/ issuers maintained risk pools that are equal to that of the general population, using various methodologies;¹⁰⁸ often to the detriment of those most in need. Passage of the Affordable Care Act on March 23, 2010, provided millions of Americans with a way to obtain, re-obtain, or keep their affordable health coverage without the fear of losing or not having it when they are at their most vulnerable.

Prior to enactment of the Affordable Care Act, an estimated 50–52 million non-elderly people lacked insurance and 50–129 million were diagnosed with a preexisting condition.¹⁰⁹ Numerous studies show that uninsured adults and children are 3 to 6 times more likely to go without or postpone receiving needed care, experience higher delays and incidences of unmet needs, have higher incidences in avoidable hospital stays, and have a higher risk of death after an accident or when hospitalized.¹¹⁰ This provision benefits and protects the millions of non-elderly persons who currently have a preexisting condition and those that will develop some condition as they age—in one study of those reporting good or excellent health, 15–30 percent will develop a preexisting condition in

¹⁰⁸ Claxton, G. and Lundy, J. How Health Care Coverage Works: A Primer 2008 Update. *The Kaiser Family Foundation*, April 2008.

¹⁰⁹ ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011; Collins, S., *et al.* Help is on the Horizon: How the Recession Has Left Millions of Workers Without Health Insurance, and How Health Reform Will Bring Relief—Findings from The Commonwealth Fund Biennial Health Insurance Survey of 2010. *The Commonwealth Fund*. 2011. Studies utilized 2008 MEPS data and The Commonwealth Biennial Health Insurance Survey of 2010 and prior years to estimate the numbers of individuals with preexisting conditions.

¹¹⁰ Collins, S., *et al.* Help is on the Horizon: How the Recession Has Left Millions of Workers Without Health Insurance, and How Health Reform Will Bring Relief—Findings from The Commonwealth Fund Biennial Health Insurance Survey of 2010. *The Commonwealth Fund*. 2011; Callahan, S., *et al.* Access to Health Care for Young Adults With Disabling Chronic Conditions. *Arch Pediatr Adolesc Med*. 2006;160:178–182; and Bernstein, J., *et al.* Issue Brief: How Does Insurance Coverage Improve Health Outcomes? *Mathematica Policy Research, Inc.* 2010:1.

the next eight years¹¹¹—by providing them a means to obtain or keep health coverage. Without the protections of these final regulations, many more Americans could be faced with the fear and anxiety of trying to obtain health coverage or faced with insufficient coverage due to preexisting conditions.

As discussed previously, those with preexisting condition exclusions or those that were uninsured could have found themselves being charged 2.5 times more prior to the Affordable Care Act.¹¹² The higher cost faced by those with preexisting conditions, whether uninsured or containing riders, could have led families to encounter financial hardships, crisis, and emotional stress.

Reports show that those lacking coverage are more likely to have trouble paying bills while being more likely to take on additional credit card debt and spend down family assets and savings, often resulting in the loss of their homes and personal bankruptcy: In 1981 the foreclosure rate reported to be associated with medical issues was only 8 percent; by 2007 this rate had increased to 62.1 percent of all personal bankruptcies, and 49 percent of foreclosures.¹¹³ These higher rates can in turn lead to many health care organizations providing uncompensated care: In 2008, the uninsured received \$116 billion worth of hospital care—the primary source of which was federal funding.¹¹⁴ In addition to their advantages with regard to access to care, health, and well-being these final regulations are likely to lower families’ out-of-pocket health care spending and the level of uncompensated care; thus benefiting State and Federal

¹¹¹ Bailey, K. Worry No More: Americans with Pre-Existing Conditions Are Protected by the Health Care Law. *Families USA*; 2012 and ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011.

¹¹² Bailey, K. Worry No More: Americans with Pre-Existing Conditions Are Protected by the Health Care Law. *Families USA*; 2012 and Anderson, G. From ‘Soak The Rich’ To ‘Soak The Poor’: Recent Trends In Hospital Pricing. *Health Affairs*; 2007; 26(3), pp. 780–789.

¹¹³ Himmelstein, D. *et al.* Medical Bankruptcy in the United States, 2007: Results of a National Study. *Am Jour of Med*. 2009; 122(8), pp. 741–746; Robertson, T., *et al.* “Get sick, get out: The medical causes of home mortgage foreclosures.” *Health Matrix: Journal of Law-Medicine*. 2008; 18(65), pp 65–105; Fact Sheet. Key Facts about the Uninsured Population. *The Kaiser Family Foundation*. October 2014; see also <https://www.medicare.gov/your-medicare-costs/help-paying-costs/medicaid/medicaid.html>.

¹¹⁴ Stoll, K. and Bailey, K. Hidden Health Tax: Americans Pay a Premium. *Families USA*, 2009 and Coughlin, T. *et al.* Uncompensated Care for Uninsured in 2013: A detailed Examination. *The Kaiser Family Foundation*, 2014.

governments and, by extension, taxpayers.

Finally, these final regulations may reduce instances of “job lock”-situations in which workers are unable to change jobs due to concerns regarding health insurance coverage for them and/or their dependents. Due to the limitations and exclusions in individual health coverage, many people were forced into a position where they chose to remain in a job out of fear of losing their existing coverage or chose a job with sponsored coverage over a higher wage position.¹¹⁵ Job lock leads to a number of labor market distortions resulting in workers in jobs that are a “poor fit,” with reduced satisfaction or skills that are not properly utilized, affecting their ability to start new businesses, retire, or reduce their work load.¹¹⁶ One study indicates that 35 percent of those surveyed worried they will have to forego job opportunities or forego retirement to maintain coverage.¹¹⁷

Under the Affordable Care Act, the interim final regulations, and these final regulations, someone currently insured through the group market with less than 18 months of continuous coverage may be more willing to leave their job and become a self-employed entrepreneur if they or their dependents have a preexisting condition—resulting in potentially 2–4 million more self-employed individuals.¹¹⁸ Similarly, even a worker with more than 18 months of continuous coverage who is already protected by HIPAA may be more likely to consider switching firms and changing policies because they will not have to worry that a preexisting condition could be excluded for up to 12 months.¹¹⁹ While the total reduction in job-lock may be small, the impact on those families with members that have preexisting conditions may be significant.

Executive Order 12866 requires agencies to take account of “distributive

¹¹⁵ GAO, Private Health Insurance: Estimates of Individuals with Preexisting Conditions Range from 36 million to 122 million. GAO-12-439, 2012.

¹¹⁶ Baker, D. Job Lock and Employer—Provided Health Insurance: Evidence from the Literature. *Public Policy Institute*. 2015;1–35; ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011; Fact Sheet. Key Facts about the Uninsured Population. *The Kaiser Family Foundation*. October 2014.

¹¹⁷ Altman, D. Pre-X Redux. *The Kaiser Family Foundation*, June 2013.

¹¹⁸ Baker, D. Job Lock and Employer—Provided Health Insurance: Evidence from the Literature. *Public Policy Institute*. 2015;1–35.

¹¹⁹ Foronstin, P. Health Insurance Portability and Job Lock: Findings from the 1998 Health Confidence Survey. *Employee Benefit Research Institute Notes*. 1998: 19(8), pp. 4–6.

impacts” and “equity.” Requiring health plans and issuers to provide coverage to adults and children with preexisting conditions will result in a small increase in premium for relatively healthy adults and children, and a large increase in health and financial security for individuals with preexisting conditions. This transfer is a meaningful increase in equity, and is a benefit of this final regulation.

3. Costs and Transfers

Although those that have preexisting condition exclusions have higher health care costs than healthier individuals, among individuals with preexisting conditions, those who are uninsured have expenditures that are somewhat lower than the average insured individual.¹²⁰ It is expected that when those individuals who are uninsured or have policies with preexisting condition exclusions gain coverage, there will be additional demand for and utilization of services, leading to a transfer from out-of-pocket spending to spending covered by insurance, which will partially be mitigated by a reduction in cost-shifting of uncompensated care to the insured population as coverage expands.

In evaluating the impact of this provision, it is important to remember that the full net effects of this provision cannot be estimated because of its interactions with other provisions in the Affordable Care Act. For example, under the current guaranteed availability and renewability protections in the individual market, children and young adults with a preexisting condition are now generally able to obtain and maintain coverage on a parental plan, where he or she can potentially stay on that plan until age 26. As another example, the Affordable Care Act requires that non-grandfathered health plans provide recommended preventive services at no cost-sharing. This will amplify the benefits of coverage for newly insured individuals with preexisting conditions. Moreover, the expansion of the preexisting condition exclusion policy occurred at the same time as other policies were implemented, such as the individual responsibility and premium tax credit provisions. Therefore, the Departments cannot provide a more precise estimation of either the benefits or the costs and transfers of this provision.

¹²⁰ Coughlin, T. *et al.* Uncompensated Care for Uninsured in 2013: A Detailed Examination. *The Kaiser Family Foundation*, 2014; GAO, Private Health Insurance: Estimates of Individuals with Preexisting Conditions Range from 36 million to 122 million, GAO-12-439, 2012.

C. PHS Act Section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815–2711, 29 CFR 2590.715–2711, 45 CFR 147.126)

1. Affected Entities and Individuals

Prior to the passage of the Affordable Care Act, both the incidence and amount of lifetime limits varied by market and plan type (e.g., HMO, PPO, POS). In the RIA for the interim final regulations, it was estimated that only 8 percent of large employers, 14 percent of small employers and 19 percent of individual market policies imposed an annual limit at that time and thus would have been directly impacted by the interim final regulations, which were phased in.

Fear and anxiety about reaching annual or lifetime limits on coverage was a major concern among Americans who have health insurance, although while such limits were relatively common in health insurance, the numbers of people expected to exceed either an annual or lifetime limit was quite low.

2. Benefits

As discussed in the RIA for the interim final regulations, annual and lifetime limits function as caps on how much a group health plan or insurance company will spend on medical care for a given insured individual over the course of a year, or the individual’s lifetime. Once a person reaches this limit or cap, the person is essentially uninsured: He or she must pay the remaining cost of medical care out-of-pocket. These limits particularly affect people with high-cost conditions,¹²¹ which typically are very serious and can lead to financial hardship. Prohibiting lifetime limits and annual limits will benefit families and individuals experiencing financial burdens due to exceeding the benefit limits of their insurance policy. By ensuring and continuing coverage, the regulations also reduce uncompensated care, which would otherwise increase premiums of the insured population through cost-shifting.

These provisions will also improve access to care. Reaching a limit could interrupt or cause the termination of needed treatment, leading to worsening of medical conditions. The removal and restriction of benefit limits helps ensure continuity of care and the elimination of the extra costs that arise when an

¹²¹ A December 2014 study by Milliman “2014 U.S. organ and tissue transplant cost estimates and discussion” found that the average 2014 billed charges related to a heart transplant is \$1,242,200, a liver transplant averaged \$739,100, while a heart-lung transplant averaged \$2,313,600.

untreated or undertreated condition leads to the need for even more costly treatment, that could have been prevented if no loss of coverage had occurred. By ensuring continuation of coverage, the regulations benefit the health and the economic well-being of participants, beneficiaries, and enrollees.

Executive Order 12866 explicitly requires agencies to take account of “distributive impacts” and “equity,” and these considerations help to motivate the relevant statutory provisions and the interim final regulations and these regulations. Prohibiting lifetime and annual limits assures that insurance will perform the function for which it was designed—namely, protecting health and financial wellbeing for those most in need of care. This represents a meaningful improvement in equity, which is a benefit associated with the regulations.

3. Costs and Transfers

As discussed in the regulatory impact analysis for the interim final regulations, extending health insurance coverage for individuals who would otherwise hit a lifetime or annual limit will increase the demand for and utilization of health care services, thereby generating additional costs to the system. The three year phase-in of the elimination of annual limits and the immediate elimination of lifetime limits increased the actuarial value of the insurance coverage for affected plans and policies if no other changes were made to the plan or policy. Issuers and plans in the group market may have chosen to make changes to the plan or policy to maintain the pre-regulation actuarial value of the plan or policy, such as changing their provider networks or copayments in some manner. To the extent that higher premiums (or other plan or policy changes) are passed on to all employees, there is an explicit transfer from workers who would not incur high medical costs to those who do incur high medical costs. If, instead, the employers do not pass on the higher costs of insurance coverage to their workers, this can result in lower profits or higher prices for the employer’s goods or services. In the individual market, when policies were individually underwritten with no rating bands in the majority of States, the Departments expected the added premium cost or other benefit changes to be largely borne by the individual policyholder. With the market reforms in place, along with single risk pool requirements, issuers can spread the increased costs across the entire individual market, leading to

a transfer from those who do not incur high medical costs to those who do incur such costs. However, as with the group market, such a transfer was expected to be modest, given the small numbers of people who were expected to exceed their benefit limits. The Departments previously estimated that the transfer would be three-quarters of a percent or less for lifetime limits and one-tenth of a percent or less for annual limits, under a situation of pure community rating where all the costs get spread across the insured population. This impact does not apply to grandfathered individual market plans.

It is worth noting that these transfers are expected to have been significantly mitigated by the associated expansion of coverage created by the interim final regulations and other regulations implementing the Affordable Care Act. The Departments expect that, as a result of the gradual elimination of annual limits and the immediate elimination of lifetime limits, fewer people have been left without protection against high medical costs. This results in fewer individuals spending down resources and enrolling in Medicaid or receiving other State and locally funded medical support. Such an effect will likely be amplified due to the high-cost nature of people who exceed benefit limits.

D. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.128)

1. Affected Entities and Individuals

PHS Act Section 2712 and these final regulations create a statutory Federal standard and enforcement power in the group and individual markets where it did not exist. Prior to this provision taking effect, varying Federal common laws existed for ERISA plans. State rules pertaining to rescission have been found to be preempted by ERISA by five circuit courts (5th, 6th, 7th, 9th and 11th as of 2008).

The Affordable Care Act and its implementing regulations should have a large effect on reducing the number of rescissions for two reasons. First, the Affordable Care Act raised the standard governing when coverage may be rescinded. Group health plans and health insurance issuers may now only rescind coverage based on fraud or intentional misrepresentation of a material fact which is a higher standard than most State laws required previously. Second, the interaction of these regulations with PHS Act sections 2704, prohibition of preexisting condition exclusions, and sections 2705, prohibiting discrimination against individual participants and

beneficiaries based on health status, could significantly reduce the number of policies rescinded. Previously, the issues surrounding the reporting of pre-existing conditions to issuers and an individual’s health status were primary causes of rescissions. With the main source of rescissions removed there would be a significant drop in rescissions even without these regulations.

The Departments assume that these final regulations will have their largest impact on the individual insurance market, because group health coverage rarely is rescinded.¹²² By creating a new Federal standard governing when policies can be rescinded, the Departments expect these final regulations to potentially affect the approximately 6.7 million non-elderly individual health insurance policies covering 10.9 million policy holders and their dependents in the individual health insurance market.¹²³ In addition, approximately 430 health insurance issuers offering coverage in the individual health insurance market who currently could rescind health insurance coverage are expected to be affected.¹²⁴ That said, the actual incidence of individuals who are subject to rescissions each year is likely to be small. The NAIC Regulatory Framework Task Force collected data on 52 companies covering the period 2004–2008, and found that rescissions averaged 1.46 per thousand policies in force.¹²⁵ These pre-Affordable Care Act estimates are believed to be a significant over-statement of rescissions occurring now, however no new data is available. Using this estimate implies that when combined with the current numbers of policy holders in the individual market there could be approximately 9,900 rescissions per year.

2. Benefits

Because there is little pre-Affordable Care Act data available and no publicly available post-Affordable Care Act data, the Departments find it difficult to estimate the benefits associated with this provision. However, the Departments believe that the benefits of this provision would accrue to those individuals who without these regulations would have their policies rescinded.

¹²² This statement is based on the Departments’ conversations with industry experts.

¹²³ 2013 filings of the Medical Loss Ratio Report found at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Medical-Loss-Ratio.html>.

¹²⁴ 2013 filings of the Medical Loss Ratio Report.

¹²⁵ NAIC Rescission Data Call, December 17, 2009, p.1.

As noted, Executive Order 12866 requires consideration of “distributive impacts” and “equity.” To the extent that rescissions are arbitrary, or targeted at those most ill, and revoke the insurance that enrollees paid for and expected to cover the cost of expensive illnesses and conditions, preventing rescissions would prevent inequity and greatly increase health and economic well-being. Consumers would have greater confidence that purchasing insurance would be worthwhile, and policies would represent better value for money.

Individuals who otherwise would have had their policies rescinded are now able to retain their coverage; the maintenance of such coverage through severe illness helps to prevent financial hardship for the enrollee and their family, creating a substantial financial benefit.¹²⁶

As discussed previously, uninsured individuals are less likely to receive needed care when they become ill, resulting in the worsening of their condition. The lack of insurance can lead to lost workplace productivity and additional mortality and morbidity. Additionally, this provision protects those individuals currently receiving treatment for a condition by eliminating the potential interruptions or terminations in care resulting from rescissions, resulting in higher losses in productivity.¹²⁷ Thus, this rule would contribute to increased worker productivity by reducing the burden associated with the loss of insurance coverage, and the concomitant financial and emotional stress.

3. Costs and Transfers

As with the benefits, the costs and transfers of these regulations are similar to those of the interim final regulations. The prohibition of rescissions except in cases of fraud or intentional misrepresentation of material fact could lead insurers to spend more resources checking applications before issuing policies than they did before the Affordable Care Act, which would increase administrative costs. However, under the final regulations, these costs could be partially offset by decreased costs associated with reduced post-claims underwriting.

¹²⁶ Girion, Lisa “Health Net Ordered to Pay \$9 million after Canceling Cancer Patient’s Policy,” *Los Angeles Times* (2008), available at: <http://www.latimes.com/business/la-fi-insure23feb23.1.5039339.story>.

¹²⁷ Collins et al. “Gaps in Health Insurance: An All American Problem” *Commonwealth Fund* (2006), available http://www.commonwealthfund.org/usr_doc/Collins_gapslhltins_920.pdf.

To the extent that continuing coverage for these generally high-cost populations leads to additional demand for and utilization of health care services, there will be additional costs generated in the health care system. However, given the relatively low rate of rescissions (approximately 0.15 percent of individual policies in force) and the relative nature of those individuals who generally have policies rescinded (who would have difficulty going without treatment), the Departments estimate that these additional costs would be small.

For those policies or plans that are rescinded, the requirement for an advance notice prior to such a rescission imposes a total hour burden of approximately 250 hours and a cost burden of approximately \$3,900. These costs are discussed in more detail in the Paperwork Reduction Act section later in this preamble.

A transfer likely will occur within the individual health insurance market from policyholders whose policies would not have been rescinded before the Affordable Care Act to some of those whose policies that would have been rescinded before the Affordable Care Act, depending on the market and the rules which apply to it. This transfer could result from higher overall premiums insurers will charge to recoup the costs associated with the health care costs of those individuals with chronic or serious conditions whose policies could previously be rescinded (the precise change in premiums depending on the competitive conditions in specific insurance markets). This transfer across the market would benefit those individuals with substantially higher medical costs, due to chronic or severe conditions, and would be attributable to insurers covering those costs associated with such individuals.

E. PHS Act Section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120)

1. Affected Entities and Individuals

Prior to implementation of the Affordable Care Act there were an estimated 6.6 million uninsured young adults age 19–26; with an estimated 3.3 million having parents with ESI and an additional 2.7 million with individual coverage, all of whom could potentially have been affected.¹²⁸ Implementation of this provision allowed 13.7 million young adults to either stay on or join their parents’ health plans (from

¹²⁸ Collins, S. and Nicholson, J. Rite of Passage: Young Adults and the Affordable Care Act of 2010. *The Commonwealth Fund*. May 2010.

November 2010 until November 2011).¹²⁹ There was a rapid response to changes in the regulations leading to large number of employers enrolling young adults,¹³⁰ with thirteen percent of small firms and 70 percent of large firms enrolling at least one young adult—small employers on average enrolled two young adults while large employers enrolled on average 492 young adults.¹³¹

Studies have shown that 2.3 million young adults were able to gain coverage since implementation of the Affordable Care Act and this provision in 2010 through the start of the open enrollment period in October 2013.¹³² The number of affected young adults has continued to increase as more employers began covering young adult dependents and those on individual grandfathered plans began changing policies to include dependents up to age 26. This has resulted in an additional 3.4 million young adults gaining coverage since October 2013, resulting in a total of an estimated 5.7 million gaining coverage from 2010 through March 2015.¹³³

2. Benefits

The benefits of these final regulations are expected to outweigh the costs to the regulated community. As of March 2015, an estimated 5.7 million additional young adults are now covered by their parents’ health plans due to the implementation of this provision.¹³⁴ Expanding coverage options for the 19–26 year old population has resulted in a decline in the number of uninsured young adults, declining to an uninsured rate of 26.7 percent in the third quarter of 2013 (before the start of the October 2013 open enrollment period).¹³⁵

Uninsured young adults are less likely to have access to care and thus delay seeking needed care,¹³⁶ leading to

¹²⁹ Collins, S. et al. Young, Uninsured and in Debt: Why Young Adults Lack Health Insurance and How the Affordable Care Act is Helping. *The Commonwealth Fund*. June 2012.

¹³⁰ Cantor, J. et al. Early Impact of the Affordable Care Act on Health Insurance Coverage of Young Adults. *Health Services Research*, 47:5 (2012):pp. 1773–1790.

¹³¹ Claxton, G. et al. Employer Health Benefits: 2011 Annual Survey. *Kaiser Family Foundation and Health Research & Education Trust*. 2011

¹³² ASPE Data Point, Health Insurance Coverage and the Affordable Care Act, September 2015.

¹³³ ASPE. Health Insurance Coverage and the Affordable Care Act. May 2015 at http://aspe.hhs.gov/sites/default/files/pdf/83966/ib_uninsured_change.pdf.

¹³⁴ Id.

¹³⁵ Ibid and Sommers, B. Number of Young Adults Gaining Insurance Due to the Affordable Care Act Now Tops 3 Million. *ASPE Issue Brief*, June 2012.

¹³⁶ Newacheck, P. et al. Health Insurance and Access to Primary Care for Children. *N Engl J Med*.

higher costs when care is received. Further, expanded coverage provides young adults with security and protection from the financial consequences of serious medical emergencies. Recent studies have found that due to the implementation of this provision there has been a decline in the number of young adults facing higher out-of-pocket expenses (greater than \$1,500);¹³⁷ benefiting them when many young adults are currently facing elevated debt burdens and low wages.¹³⁸

Additionally, expanding coverage to those aged 19–26 should decrease the cost-shifting of uncompensated care onto those with coverage (including \$147 million from emergency department care),¹³⁹ increase the receipt of preventive health care and provide more timely access to high quality care, resulting in a healthier population. In particular, children with chronic conditions or other serious health issues will be able to continue coverage through a parent's plan until age 26.

Extending dependent coverage of children to age 26 will also permit greater job mobility for this population as their health coverage will no longer be tied to their jobs, thus reducing the potential of “job lock”,¹⁴⁰ or student status.

3. Costs and Transfers

Estimates for the incremental annual premium costs for the newly covered individuals were developed in the interim final regulations; estimating that for those enrolling in their parents' ESI, the expected annual premium cost would lead to an expected increase of 0.7 percent in 2011, 1.0 percent in 2012, and 1.0 percent in 2013. A recent study carried out by Depew and Bailey found that the requirement dependent coverage provision led to a 2.5–2.8 percent increase in premiums for plans that cover children, and that employers

did not pass on the entire premium increase to employees in the form of higher required plan contributions.¹⁴¹ To the extent that some of these increases are passed on to workers in the form of higher premiums for all workers purchasing family policies or in the form of lower wages for all workers, there will be a transfer from workers who do not have newly covered dependents to those who do. To the extent that these higher premiums result in lower profits or higher prices for the employer's product, the higher premiums will result in a transfer either from stockholders or consumers to workers who have newly covered dependents.

In addition, to the extent these final regulations result in a decrease in the number of uninsured, the Departments expect a reduction in uncompensated care, and a reduction in liability for those who fund uncompensated care, including public programs (primarily Medicaid and State and local general revenue support for public hospitals), as well as the portion of uncompensated care that is paid for by shifting costs from private payers. Such effects would lead to lower premiums for the insured population, both with or without newly covered children.

For the number of young adults enrolling in their parents' non-group (individual) insurance policy, the Departments estimated that, to a large extent, premiums in the individual market will be borne by the parents who are purchasing the coverage. If, instead, these costs are distributed over the entire individual market (as would be the case in a pure community rated market), the Departments estimated in the interim final regulations that the individual premiums would rise 0.7 percent in 2011, 1.0 percent in 2012, and 1.2 percent in 2013. However, the Departments expected the actual increase across the entire individual market, if any, to be much smaller than these estimates, because they expected the costs to be largely borne by the subscribers who are directly affected rather than distributed across the entire individual market.

F. PHS Act Section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, 45 CFR 147.136)

1. Estimated Number of Affected Entities

These provisions are applicable to non-grandfathered health plans and coverage. Using the estimates from the discussion of affected entities for the grandfathering provisions discussed in paragraph III.C, there are 96.3 million individuals covered by non-grandfathered ERISA-covered health plans, 30.4 million individuals covered by non-grandfathered State and local health plans, and 8.7 million individuals in non-grandfathered health coverage in the individual market.

Not all potentially affected individuals will be affected equally by these final regulations. Sponsors of ERISA-covered group health plans were required to implement an internal appeals process that complied with the DOL claims procedure regulation before the Affordable Care Act's enactment, and the Departments also understand that many non-Federal governmental plans and church plans that are not subject to ERISA had implemented internal claims and appeals processes that comply with the DOL claims procedure regulation. Therefore, participants and beneficiaries covered by such plans only will be affected by the internal claims and appeals standards that are provided by the Secretary of Labor in paragraph (b)(2)(ii) of these final regulations under PHS Act section 2719.

These final regulations will have the largest impact on individuals covered in the individual health insurance market, because with the issuance of the interim final regulation, these issuers were required to comply with the DOL claims procedure regulation for internal claims and appeals as well as the additional standards added by the Secretary of the Department of Health and Human Services in paragraph (b)(3) of these final regulations that are in some cases more protective than the ERISA standard.

On the external appeals side, before the enactment of the Affordable Care Act, issuers offering coverage in the group and individual health insurance market were already required to comply with State external review laws. At that time, all States except Alabama, Mississippi, Nebraska, North Dakota, South Dakota, and Wyoming had external review laws, and thirteen States had external review laws that apply only to certain market segments (for example, managed care or HMOs).

338:8 (1998) and Sommers, B. *et al.* The Affordable Care Act Has Led To Significant Gains in Health Insurance and Access to Care for Young Adults. *Health Affairs*, 32:1 (2013):pp. 165–174.

¹³⁷ Busch, S. *et al.* ACA Dependent Coverage Provision Reduced High Out-Of-Pocket Health Care Spending For Young Adults. *Health Affairs*, 33:8 (2014): pp. 1361–1366 and Mulcahy, A. *et al.* Insurance Coverage of Emergency Care for Young Adults under Health Reform. *N Engl J Med*. 368:22 (2013).

¹³⁸ Chua, K-P. and Sommers, B. Changes in Health and Medical Spending Among Young Adults Under Health Reform. *JAMA*, 311:23 (2014).

¹³⁹ Mulcahy, A. *et al.* Insurance Coverage of Emergency Care for Young Adults under Health Reform. *N Engl J Med*. 368:22 (2013).

¹⁴⁰ Sommers, B. *et al.* The Affordable Care Act Has Led To Significant Gains in Health Insurance and Access to Care for Young Adults. *Health Affairs*, 32:1 (2013):pp. 165–174.

¹⁴¹ Depew, B. and Bailey, J. Did the Affordable Care Act's dependent coverage mandate increase premiums? *Journal of Health Economics*, 41 (2015):pp. 1–14

Currently, all States except, Alabama, Alaska, Florida, Georgia, Pennsylvania, and Wisconsin have State external review laws that satisfy the requirement to provide a NAIC-similar or NAIC-parallel external review process. These six States that do not meet the requirements, must use the HHS-administered process or must contract with accredited independent review organizations to review external appeals on their behalf until they meet the requirements.¹⁴²

Individuals participating in ERISA-covered self-insured group health plans will be among those most affected by the external review requirements contained in these final regulations, because the preemption provisions of ERISA prevent a State's external review process from applying directly to an ERISA-covered self-insured plan. These plans will now be required to comply with the Federal external review process set forth under paragraph (d) of these final regulations.

In summary, the number of affected individuals depends on several factors, including whether (i) a health plan retains its grandfather status, (ii) the plan is subject to ERISA, (iii) benefits provided under the plan are self-funded or financed by the purchase of an insurance policy, (iii) the applicable State has enacted an internal claims and appeals law, and (iv) the applicable State has enacted an external review law, and if so the scope of such law, and (v) the number of new plans and enrollees in such plans.

The following, is a summary of the benefits and costs as discussed in the interim final regulations and that are still applicable to these final regulations.

2. Benefits

Because of data limitations and a lack of effective measures, the Departments did not attempt to quantify the expected benefits. Nonetheless, the Departments were able to identify several of the interim final regulation's major economic benefits.

The interim final regulations and these final regulations will help transform the current, highly variable health claims and appeals process into a more uniform and structured process. This will:

- Improve the extent to which employee benefit plans provide benefits consistent with the established terms of the plan;

- ensure greater certainty and consistency in the handling of benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated;

- increase efficiency in the operation of employee benefit plans and health care delivery as well as health insurance and labor markets;

- increase efficiency of health plans by enhancing their transparency and fostering participants' confidence in the plan's fairness;

- reduce delays and inappropriate denials;

- reduce the levels of error in the system and improve health outcomes;

- improve health care, health plan quality, and insurance market efficiency by serving as a communication channel, providing feedback from participants, beneficiaries, and providers to plans about quality issues; and

- enhance some insurers' and group health plans' abilities to effectively control costs by limiting access to inappropriate care.

3. Costs and Transfers

The Departments have quantified the primary source of costs associated with these final regulations that will be incurred to (i) administer and conduct the internal and external review process, and (ii) prepare and distribute required disclosures and notices. These costs and the methodology used to estimate them are discussed under the Paperwork Reduction Act section. The total cost related to the information collections is \$160.1 million annually.

a. Additional Requirements for Group Health Plans

Paragraph (b)(2)(i) of these final regulations imposes additional requirements to the DOL claims procedure regulation that must be satisfied by group health plans and issuers offering group and individual coverage in the individual and group health insurance markets. The Departments believe that the additional requirements have modest costs associated with them, because they merely clarify provisions of the DOL claims procedure regulation.

As discussed in the impact analysis for the interim final regulations the Departments were not able to estimate the costs for some of the requirements, namely for: the definition of adverse determination, expedited notification of benefit determination involving urgent care, eliminating conflicts of interest, and deemed exhaustion of internal process. The Departments were able to quantify the costs for Full and fair

review and Enhanced notice with culturally and linguistically appropriate notices. These costs are included in the Paperwork Reduction Act Section.

b. Additional Requirements for Issuers in the Individual Insurance Market

To address certain relevant differences in the group and individual markets, health insurance issuers offering individual health insurance coverage must comply with three additional requirements. First, these final regulations expand the scope of the group health coverage internal claims and appeals process to cover initial eligibility determinations.

This protection is important since eligibility determinations in the individual market are frequently based on the health status of the applicant, including preexisting conditions. The Departments do not have sufficient data to quantify the costs associated with this requirement.

Second, although the DOL claims procedure regulation permits group health plans to have a second level of internal appeals, these final regulations require health insurance issuers offering individual health insurance coverage to have only one level of internal appeals. This allows the claimant to seek either external review or judicial review immediately after an adverse determination is upheld in the first level of internal appeals. The Departments have factored this cost into their estimate of the cost for issuers offering coverage in the individual market to comply with this requirement.

Finally, these final regulations require health insurance issuers offering individual health insurance coverage to maintain records of all claims and notices associated with their internal claims and appeals processes. An issuer must make such records available for examination upon request. Accordingly, a claimant or State or Federal agency official generally would be able to request and receive such documents free of charge. The Departments believe that minimal costs are associated with this requirement, because most issuers retain the required information in the normal course of their business operations.

c. External Appeals

The analysis of the cost associated with implementing an external review process under the interim final regulations and these final regulations focuses on the cost incurred by the following three groups that were not required to implement an external review process before the enactment of the Affordable Care Act: Plans and participants in ERISA-covered self-

¹⁴² Affordable Care Act: Working with States to Protect Consumers, available at https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.

insured plans; plans and participants in States with no external review laws; and plans and participants in States that have State laws only covering specific market segment (usually HMOs or managed care coverage).

The Departments estimate that there are approximately 78.7 million participants in self-insured ERISA-covered plans and approximately 15.5 million participants in self-insured State and local governmental plans. In the States which currently have no external review laws or whose laws do not meet the federal minimum requirements¹⁴³ there are an estimated 13.8 million participants (8.1 million participants in ERISA-covered plans, 3.7 million participants in governmental plans and 2 million individual covered by policies in the individual market). These estimates lead to a total of 108 million participants, however, only the 80.0 million participants in non-grandfathered plans will be required to be covered by the external review requirement.

The Departments assume that there are an estimated 1.3 external appeals for every 10,000 participants¹⁴⁴, and that there will be approximately 10,400 external appeals annually. As required by these final regulations or applicable State law, plans or issuers are required to pay for most of the cost of the external review while claimants may be charged a nominal filing fee in States that authorized such fees as of November 18, 2015. One study found that the average cost of a review was approximately \$665.¹⁴⁵ The average cost per appeal in the HHS-administered External Review Program is approximately \$625 for a standard case and \$825 for an expedited case.¹⁴⁶

The actual cost per review will vary by State and type of review (standard or expedited). Lacking data on the percent of appeals that are expedited, but with the majority of appeals being standard appeals, the higher cost per appeal of \$665 for a standard appeal is used as an estimate for all appeals. These estimates lead to an estimated cost of the external

review of \$6.9 million (10,400 reviews * \$665) annually.

On average, about 40 percent of denials are reversed on external appeal.¹⁴⁷ An estimate of the dollar amount per claim reversed is \$12,500.¹⁴⁸ This leads to \$53.5 million in additional claims being reversed by the external review process annually. While this amount is a cost to plans, it represents a payment of benefits that should have previously been paid to participants, but was denied. Part of this amount is a transfer from plans and issuers to those now receiving payment for denied benefits. Part of the amount could also be a cost if the reversal leads to services and hence resources being utilized now that had been denied previously. The Departments are not able to distinguish between the two types but believe that most reversals are associated with a transfer.

These final regulations also require claimants to receive a notice informing them of the outcome of an appeal and/or external review. The independent review organization that conducts the external review is required to prepare the notice; therefore, the cost of preparing and delivering this notice is included in the fee paid them by the insurer to conduct the review.

4. Summary

These final rules extend the protections of the DOL claims procedure regulation to non-Federal governmental plans, and the market for individual coverage. Additional protections are added that cover these two markets and in addition to the market for ERISA-covered plans. These final regulations also extend the requirement to provide an independent external review. The Departments estimate that the total costs for these final regulations is \$169.9 million annually with a transfer from the plan and its participants to those whose claims are reversed of \$53.5 million annually.

G. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138)

1. Designation of Primary Care Provider

The statute, the interim final regulations and these final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage,

requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee based on his or her geographic location.

a. Affected Entities and Individuals

Choice or assignment of a primary care provider is typically required by Health Maintenance Organizations (HMOs) and Point of Service plans (POS). Recent data suggest that there are 316,000 HMOs in the United States, accounting for more than 11.3 million enrollees with ESI. There are also 558,000 POS plans accounting for almost 7 million enrollees with ESI. The individual market includes 130,700 HMO policies.¹⁴⁹ Similar data do not exist for POS policies in the individual market.

This provision only applies to non-grandfathered health plans. However, due to the lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number enrollees and plans that would be affected by this provision. Moreover, there is no data on the number of plans that auto-assigned patients to primary care physicians and did not already allow patients to make the final provider choice, as this would be the population to benefit maximally from the interim final rules and these regulations. From conversations with industry experts the Departments expect, however, that this number would be very small, and therefore the benefits and costs of this provision would be small as well.

b. Benefits, Costs, and Transfers

As discussed in the RIA for the interim final regulations, provider choice allows patients to take into account factors they may value when choosing their provider, such as provider credentials, office hours and location, advice from professionals, and information on the experience of other patients. Provider choice is a strong predictor of patient trust in their provider, which could lead to decreased

¹⁴³ These states are Alabama, Alaska, Florida, Georgia, Pennsylvania, and Wisconsin. See Affordable Care Act: Working with States to Protect Consumers, available at https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html

¹⁴⁴ AHIP Center for Policy and Research, "An Update on State External Review Programs, 2006," July 2008.

¹⁴⁵ North Carolina Department of Insurance "Healthcare Review Program: Annual Report," 2013 Table 4. <http://www.ncdoi.com/smart/Documents/ExternalReviewReport16.pdf>

¹⁴⁶ The HHS-administered External Review Program is approximately \$625 for a standard case and \$825 for an expedited case.

¹⁴⁷ Of the 105 cases fully reviewed in the HHS-administered external review process so far, 28 have been overturned and 25 have been partially overturned.

¹⁴⁸ North Carolina Department of Insurance "Healthcare Review Program: Annual Report," 2013. <http://www.ncdoi.com/smart/Documents/ExternalReviewReport16.pdf>

¹⁴⁹ Data for the group market (plan and participant counts) were calculated using the 2012 MEPS, 2012 Census of Government, 2014 Current Population Survey, and 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits. Data for the individual market were calculated using AHIP "Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits," Table 10 and Medical Loss Ratio submissions for 2013 reporting year.

likelihood of malpractice claims, improved medication adherence and also improves health outcomes.

Although difficult to estimate given the data limitations described, the costs for this provision are likely to be minimal. As noted in the RIA for the interim final regulations, when enrollees like their providers, they are more likely to maintain appointments and comply with treatment, both of which could induce demand for services, but these services could then in turn reduce costs associated with treating more advanced conditions. However, the number of affected entities from this provision is very small, leading to small additional costs. There will likely be negligible transfers due to this provision given no changes in coverage or cost-sharing.

2. Designation of Pediatrician as Primary Care Provider

If a plan or issuer 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 designation of 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. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusions with respect to coverage of pediatric care.

a. Affected Entities and Individuals

Due to lack of data on enrollment in managed care organizations by age, as well as lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number of enrollees and plans that would be affected by these provisions. As a reference, there are an estimated 5.6 million individuals under age 19 with ESI who are in an HMO plan.¹⁵⁰

b. Benefits, Costs, and Transfers

By expanding participating primary care provider options for children to include pediatricians, this provision benefits individuals who are making decisions about care for their children. As discussed in the previous section,

research indicates that when doctors and patients have a strong, trusting relationship, patients often have improved medication adherence, health promotion, and other beneficial health outcomes.

In addition, allowing enrollees to select a physician specializing in pediatrics as their children's primary care provider has removed any referral related delays for individuals in plans that required referrals to pediatricians and did not allow physicians specializing in pediatrics to serve as primary care providers. The American Academy of Pediatrics (AAP) strongly supports the idea that the choice of primary care clinicians for children should include pediatricians.¹⁵¹ Regular pediatric care, including care by physicians specializing in pediatrics, can improve child health outcomes and avert preventable health care costs.

Giving enrollees in covered plans (that require the designation of a primary care provider) the ability to select a participating pediatrician as the child's primary care provider benefits those individuals who would not otherwise have been given this choice. Again, the extent of these benefits will depend on the number of enrollees with children that are covered by plans that do not allow the selection of a pediatrician as the primary care provider, which industry experts suggest would be small.

Although difficult to estimate given the data limitations described, the costs for this provision are likely to be small. Giving enrollees a greater choice of primary care providers by allowing them to select participating physicians who specialize in pediatrics as their child's primary care provider could lead to increased health care costs by increasing the take-up of primary care services, assuming they would not have utilized appropriate services as frequently if they had not been given this choice.

Any transfers associated with the interim final regulations and these final regulations are expected to be minimal. To the extent that pediatricians acting as primary care providers would receive higher payment rates for services provided than would other primary care physicians, there may be some transfer of wealth from policy holders of non-grandfathered group plans to those enrollees that choose the former providers. However, the Departments do

not believe that this is likely given the similarity in income for primary care providers that care for children.

3. Patient Access to Obstetrical and Gynecological Care

The statute, the interim final regulations and these final regulations also provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. Specifically, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology (OB/GYN). These plans and issuers must also treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the OB/GYN as the authorization of the primary care provider. For this purpose, an OB/GYN is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

a. Affected Entities and Individuals

Requiring referrals or authorizations to OB/GYNs is typically required by HMOs and POS plans.

This provision applies to non-grandfathered health plans. However, due to the lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number of enrollees and plans that would be affected by this provision. As a reference, there are an estimated 7.3 million females between ages 21 to 65 with ESI who are in HMO plans.¹⁵²

b. Benefits, Costs, and Transfers

This provision gives women in covered plans easier access to their OB/GYNs, where they can receive preventive services such as pelvic and breast exams, without the added time, expense, and inconvenience of needing permission first from their primary care providers. Moreover, this provision may also save time and reduce administrative burden since participating OB/GYNs do not need to

¹⁵⁰ Estimate based on data from the 2012 MEPS, 2012 Census of Government, 2014 Current Population Survey, and 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits.

¹⁵¹ See AAP Policy Statement, "Guiding Principles for Managed Care Arrangements for the Health Care of Newborns, Infants, Children, Adolescents, and Young Adults", available at: <http://pediatrics.aappublications.org/content/132/5/e1452.full.pdf+html>.

¹⁵² Estimate based on data from the 2012 MEPS, 2012 Census of Government, 2014 Current Population Survey, and 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits.

get an authorization from a primary care provider to provide care and order obstetrical and gynecological items and services. To the extent that primary care providers spend less time seeing women who need a referral to an OB/GYN, access to primary care providers will be improved. To the extent that the items and services are critical and would have been delayed while getting an authorization from the primary care provider, this provision will improve the treatment and health outcomes of female patients. Access to such care can have substantial benefits in women's lives.

To the extent that direct access to OB/GYN services results in increased utilization of recommended and appropriate care, this provision may result in benefits associated with improved health status for the women affected. Potential cost savings also exist since women in affected plans will not need to visit their primary care provider in order to get a referral for routine obstetrical and gynecological care, items, and services, thereby reducing unnecessary time and administrative burden, and decreasing the number of office visits paid by her and by her health plan.

One potential area of additional costs associated with this provision would be induced demand, as women who no longer need a referral to see an OB/GYN may be more likely to receive preventive screenings and other care. Data is limited to provide an estimate of this induced demand, but the Departments believe it to be small.

To the extent this provision results in a shift in services to higher cost providers, it will result in a transfer of wealth from enrollees in non-grandfathered group plans to those individuals using the services affected. However, such an effect is expected to be small.

4. Emergency Services

PHS Act section 2719A, the interim final regulations, and these final regulations provide that a group health plan and a health insurance issuer covering emergency services must do so without the individual or the health care provider having to obtain prior authorization (even if the emergency services are provided out-of-network). For a plan or health insurance coverage with a network of providers that provide benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or

limitations that apply to in-network emergency services.

Finally, the interim final regulations and these final regulations provide that cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. The regulations also provide that a plan or health insurance issuer provide benefits for out-of-network emergency services (prior to imposing in-network cost sharing) in an amount at least equal the greatest of: (1) The median amount negotiated with in-network providers for the emergency service; (2) 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); or (3) the amount that would be paid under Medicare for the emergency service. In applying the rules relating to emergency services, the statute and the regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act.

The statute and the regulations relating to emergency services do not apply to grandfathered health plans; however, other Federal or State laws related to emergency services may apply regardless of grandfather status.

a. Affected Entities and Individuals

The interim final regulations and these regulations directly affect out-of-pocket expenditures for individuals enrolled in non-grandfathered private health plans (group or individual) whose copayment or coinsurance arrangements for emergency services differ between in-network and out-of-network providers. These regulations may also require some health plans to change the amount they pay to out-of-network providers compared to their pre-Affordable Care Act contractual arrangements. There are no available data, however, that allow for national estimates of the number of plans (or number of enrollees in plans) that have different payment arrangements for out-of-network than in-network providers, or differences between in- and out-of-network copayment and coinsurance arrangements, in order to more precisely estimate the number of enrollees affected.

Prior to the issuance of the interim final regulations, the Departments

conducted an informal survey of benefits plans for large insurers in order to assess the landscape with regard to copayment and coinsurance for emergency department services, but found that a variety of arrangements existed in the marketplace prior to the issuance of the interim final regulations. Many of the large insurers maintained identical copayment and/or coinsurance arrangements between in- and out-of-network providers. Others had differing arrangements based on copayments, coinsurance rates, or a combination of the two. While useful for examining the types of arrangement that exist in the market place, these data do not contain enrollment information and therefore cannot be used to make impact estimates.

It was estimated in the interim final regulations that a maximum of 2.1 to 4.2 million individuals would be potentially affected by differing out-of-pocket requirements. Based on an informal survey, some proportion, possibly a large portion, of these individuals were covered by plans that had identical in- and out-of-network requirements. Therefore, the number of individuals affected by this regulatory provision was expected to be smaller.

b. Benefits, Costs, and Transfers

Insurers maintained differing copayment and coinsurance arrangements between in- and out-of-network providers as a cost containment mechanism. Implementing reduced cost sharing for the use of in-network providers provides financial incentive for enrollees to use these providers, with whom plans often have lower-cost contractual arrangements. In emergency situations, however, the choice of an in-network provider may not be available—for example, when a patient is some distance from his or her local provider networks or when an ambulance transports a patient to the nearest hospital which may not have contractual arrangements with the person's insurer. In these situations, the differing copayment or coinsurance arrangements could place a substantial financial burden on the patient. This provision eliminates this disparity in out-of-pocket burden for enrollees, leading to potentially substantial financial benefit.

The regulations also provide for potentially higher payments to out-of-network providers, if usual customary rates or Medicare rates are higher than median in-network rates. This can have a direct economic benefit to providers and patients, as the remaining differential between provider charge and plan payment will be smaller,

leading to a smaller balance-bill for patients.

To the extent that expectations about such financial burden with out-of-network emergency department usage would cause individuals to delay or avoid seeking necessary medical treatment when they cannot access a network provider, this provision may result in more timely use of necessary medical care. It may therefore result in health and economic benefits associated with improved health status; and fewer complications and hospitalizations due to delayed and possibly reduced mortality. The Departments expect that this effect would be small, however, because insured individuals are less likely to delay care in emergency situations.

The economic costs associated with the emergency services provisions are likely to be minimal. These costs will occur to the extent that any lower cost-sharing will induce new utilization of out-of-network emergency services. Given the nature of these services as emergency services, this effect is likely to be small for insured individuals. In addition, the demand for emergency services in truly emergency situations can result in health care cost savings and population health improvements due to the timely treatment of conditions that could otherwise rapidly worsen.

As discussed in the RIA for the interim final regulations, the emergency services provisions are likely to result in some transfers from the general membership of non-grandfathered group health plans that have differing copayment and coinsurance arrangements to those policy holders that use the out-of-network emergency services. The precise amount of the transfer which would occur through an increase in premiums is impossible to quantify due to lack of data, but only applies to non-grandfathered health plans.

5. Application to Grandfathered Plans

The provisions relating to certain patient protections do not apply to grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

6. Patient Protection Disclosure Requirement

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or

(2) obtain obstetrical or gynecological care without prior authorization.

Accordingly, as was provided in the interim final regulations, these final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in these regulations. The notice must be provided 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, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

The Departments estimate that the cost to plans and insurance issuers to prepare and distribute the disclosure is \$940,000 in 2015. For a discussion of the Patient Protection Disclosure Requirement, see the Paperwork Reduction Act section later in this preamble.

IV. Paperwork Reduction Act

A. Departments of Labor and the Treasury

These final regulations contain a notice of grandfather status and third party disclosure, rescissions notice, and patient protection disclosures requirement for issuers and notice requirements related to internal claims and appeals and external review that are information collection requests (ICRs) subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)).

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)), the Departments submitted an ICR to OMB in accordance with 44 U.S.C. 3507(d), contemporaneously with the publication of the interim final regulations, for OMB's review under the emergency PRA Procedures.¹⁵³ OMB subsequently approved the ICRs. Contemporaneously with the publications of the emergency ICRs, the Departments published a separate **Federal Register** notice informing the public that it intended to request OMB to extend the approval for three years and soliciting comments on the ICRs. OMB approved the ICR extensions.

No public comments were received in response to the ICRs contained in the interim final regulations that specifically addressed the paperwork burden analysis of the information collections. The comments that were submitted contained information

relevant to the costs and administrative burdens attendant to the proposals. The Departments took into account the public comments when analyzing the economic impact of the proposals, and developing the revised paperwork burden analysis, which is summarized in the following sections.

A copy of the ICRs may be obtained by contacting the following PRA addressee or at <http://www.RegInfo.gov>. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N-5718, Washington, DC 20210. Telephone: (202) 693-8410; Fax: (202) 219-4745. These are not toll-free numbers. Email: ebbsa.opr@dol.gov.

1. ICR Regarding Affordable Care Act Notice of Grandfather Status and Third Party Disclosure

As discussed earlier in this preamble, to maintain grandfathered health plan status under these final regulations, a plan or issuer must maintain records that document the plan or policy terms 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, disclose its status as a grandfathered health plan, and if switching issuers and intending to maintain its status as a grandfathered plan it must provide to the new health insurance issuer documentation of plan terms under the prior health coverage sufficient for it to determine whether a change causing a cessation of grandfathered health plan status has occurred.

a. Grandfathered Health Plan Disclosure

The final regulations provide that the plan or issuer of a grandfathered plan must disclose to participants and beneficiaries its status as a grandfathered health plan. Model language is provided by the Departments. Using data from the 2014 Employer Health Benefits Survey it is estimated that 37 percent of plans are grandfathered plans and 26 percent of employees in ERISA-covered plans are in a grandfathered plans.¹⁵⁴

The Departments estimate that there are 850,700 (2.3 million ERISA-covered plans * 0.37) ERISA-covered plans¹⁵⁵—with an estimated 17.2 million policy holders (66 million policy holders * 0.26)—that will need to include the

¹⁵⁴ Kaiser Family Foundation, "2014 Employer Health Benefits Survey." <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/>.

¹⁵⁵ EBSA estimates based on the 2014 Medical Expenditure Survey—Insurance Component.

¹⁵³ 5 CFR 1320.13.

notice in plan documents.¹⁵⁶ After plans satisfied the grandfathered health plan disclosure requirement in 2011, any additional burden should be de minimis if a plan wants to maintain its grandfathered status in future years. The Departments also expect the cost of removing the notice from plan documents as plans relinquish their grandfathered status to be de minimis and therefore it is not estimated. Based on the foregoing, the Departments estimate that plans will incur no additional burden to maintain or remove the notice from plan documents.

The Departments estimate that the notice will require one-half of a page and five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically. This results in a total cost burden of approximately \$266,000 (\$0.05 per page*1/2 pages per notice * 17.2 million notices*0.62).

b. Record Keeping Requirement

Plans were required to maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010.

The Departments assume that most of the documents required to be retained to satisfy the recordkeeping requirement of these final regulations are already retained by plans for tax purposes, to satisfy ERISA's record retention and statute of limitations requirements, and for other business reasons. The Departments estimated this as a one-time cost incurred in 2011, because after the first year, the Departments anticipate that any future costs to retain the records will be de minimis.

c. Documentation of Plan Terms

These final regulations contain a disclosure requirement that requires that a group health plan that is changing health insurance coverage to provide to the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph (g)(1) under the Affordable Care Act section 1251 regulations are exceeded. The number of plans that might be effected (133,200) is estimated by multiplying the number of grandfathered plans (850,700) by the percent of plans shopping for a new

carrier (58 percent) and the number of plans shopping for a new carrier that switched (27 percent). Each of these plans would need to transmit to the carrier documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph (g)(1) of the final regulations under Affordable Care Act section 1251 are exceeded. It is estimated that the electronic transmission of the already retained documents would require 2 minutes of a clerical staff's time with a labor rate of \$30.42 per hour.¹⁵⁷ These estimate result in an hour burden of 4,440 hours (133,200*2/60) with an equivalent cost of \$135,100 (133,200*2/60*\$30.42). Each of these plans would need to transmit to the carrier documentation of plan terms. If half of the plans transmit the required documents electronically then 66,600 plans will be sent via mail resulting in a materials and postage costs of \$467,600 ((66,600*(90 pages * 5 cents per page + \$2.52 postage)).

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with an ICR unless the ICR has a valid OMB control number.

The paperwork burden estimates are summarized as follows:

Type of Review: Revision.

Agency: Employee Benefit Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Disclosure and Recordkeeping Requirements for Grandfathered Plans under the Affordable Care Act.

OMB Control Number: 1210-0140; 1545-2178.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 850,700.

Total Responses: 18,143,923.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours (three year average): 2,200 (Employee Benefits Security Administration); 2,200 (Internal Revenue Service).

Estimated Total Annual Cost Burden (three year average): \$366,800 (Employee Benefits Security Administration); \$366,800 (Internal Revenue Service).

2. ICR Regarding Affordable Care Act Notice Relating to Rescissions

As discussed earlier in this preamble, PHS Act Section 2712 and these final regulations provide rules regarding rescissions for group health plans and health insurance issuers that offer group or individual health insurance coverage. A plan or issuer must not rescind coverage under the plan, policy, certificate, or contract of insurance except in the case of fraud or intentional misrepresentation of a material fact. These final regulations provide that a group health plan or a health insurance issuer offering group health insurance coverage must provide at least 30 calendar days advance notice to an individual before coverage may be rescinded. This rescission notice requirement is an information collection request (ICR) subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)).

The Departments assume that rescissions are rare in the group market and that small group health plans are affected by rescissions. The Departments are not aware of a data source on the number of group plans whose policy is rescinded; therefore, the Departments assume that 100 small group health plan policies are rescinded in a year. The Departments estimate that there is an average of 15.33 participants in small, insured plans.¹⁵⁸ Based on these numbers the Departments estimate that approximately 100 policies are rescinded during a year, which would result in 1,533 notices being sent to affected participants with 38 percent transmitted electronically and 62 percent mailed. The Departments estimate that 15 minutes of legal professional time at \$129.94 per hour would be required by the insurers of the 100 plans to prepare the notice and one minute per notice of clerical professional time at \$30.42 per hour would be required to distribute the paper notices. The Departments believe

¹⁵⁸ U.S. Department of Labor, EBSA calculations using the March 2014 Current Population Survey Annual Social and Economic Supplement and the 2012 Medical Expenditure Panel Survey.

¹⁵⁶ Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2014 Annual Social and Economic Supplement to the Current Population Survey, Table 3C.

¹⁵⁷ The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/pdf/ocwage.pdf>); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/ecec.t02.htm>); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 <http://www.bls.gov/news.release/eci.nr0.htm>). Secretaries, Except Legal, Medical, and Executive (43-6014): \$16.35(2013 BLS Wage rate)/0.675(ECEC ratio) *1.2(Overhead Load Factor) *1.023(Inflation rate) - 2(Inflated 2 years from base year) = \$30.42.

the costs of electronic transmission would be de minimis. This results in an hour burden of approximately 41 hours with an equivalent cost of approximately \$3,700.¹⁵⁹

The Departments estimate that the cost burden associated with distributing the paper notices via mail will be approximately \$500. This results from distributing 950 paper notices at a cost of \$0.54 per notice.¹⁶⁰

These paperwork burden estimates are summarized as follows:

Type of Review: Revision of existing collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Required Notice of Rescission of Coverage under the Patient Protection and Affordable Care Act Disclosures.

OMB Number: 1210–0141; 1545–2180.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 100.

Total Responses: 1,533.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 20.5 hours (Employee Benefits Security Administration); 20.5 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: \$250 (Employee Benefits Security Administration); \$250 (Internal Revenue Service).

3. ICR Regarding Affordable Care Act Patient Protection Disclosure Requirement

a. Patient Protection Disclosure

As discussed earlier in this preamble, PHS Act section 2719A imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of health care professionals. When applicable, it is important that individuals enrolled in a plan or health

¹⁵⁹ The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/pdf/ocwage.pdf>); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/ecec.t02.htm>); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 <http://www.bls.gov/news.release/eci.nr0.htm>).

¹⁶⁰ This estimate is based on an average document size of one page, \$.05 cents per page material and printing costs, and \$0.49 postage costs.

insurance coverage know of their rights to (1) Choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; (2) obtain obstetrical or gynecological care without prior authorization; or (3) coverage of emergency services. Accordingly, these final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscriber) of these rights when applicable. Model language is provided in these final regulations. The notice must be provided 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, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance. The Affordable Care Act patient protection disclosure requirement is an ICR subject to the PRA.

In order to satisfy these final regulations' patient protection disclosure requirement, the Departments estimate that 41,000 ERISA-covered plans will need to notify an estimated 693,000 policy holders annually of their plans policy in regards to designating a primary care physician and for obstetrical or gynecological visits.¹⁶¹ The Departments believe that plans would only incur costs associated with this notice during the first year after relinquishing grandfather status. In subsequent years, this notice would remain unchanged and its costs are factored into the burden estimates associated with the Summary Plan Description information collection request (OMB Control Number 1210–0039).

The following estimates are based on the assumption that five percent of group health plans will relinquish grandfathered health plan status annually. Because the final regulations provide model language for this purpose, the Departments estimate that five minutes of clerical time (with a labor rate of \$30.42/hour) will be required to incorporate the required

¹⁶¹ The Departments' estimate of the number of ERISA-covered health plans was obtained from the 2014 Medical Expenditure Survey—Insurance Component and the number of policy holders was obtained from the Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2014 Annual Social and Economic Supplement to the Current Population Survey, Table 3C <http://www.dol.gov/ebsa/pdf/coveragebulletin2014.pdf>. Information on HMO and POS plans and enrollment in such plans was obtained from the Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2014. The Department assumes that five percent of group health plans will relinquish grandfathered health plan status annually.

language into the plan document and ten minutes of a human resource professional's time (with a labor rate of \$110.30/hour) will be required to review the modified language. Therefore, the Departments estimate that plans relinquishing grandfathered health plan status will incur an annual hour burden of 10,000 hours with an equivalent cost of \$866,000.¹⁶²

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Departments estimate that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically at de minimis cost. This results in a cost burden of \$11,000.¹⁶³

b. Out-of-Network Emergency Services Disclosure

The final regulations require that a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is more restrictive than the copayment or coinsurance requirement that would apply if the services were provided in network. If State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, the plan or issuer must provide an enrollee or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by an enrollee or beneficiary. This information should already be routinely included in the Explanation of Benefit documents

¹⁶² The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/pdf/ocwage.pdf>); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/ecec.t02.htm>); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 <http://www.bls.gov/news.release/eci.nr0.htm>).

¹⁶³ This estimate is based on an average document size of ½ page, \$.05 cents per page material and printing costs, and \$0.49 postage costs for paper notices and de minimis costs for electronically distributed notices. The Departments assume 62 percent of notices will be on paper and 38 percent will be distributed electronically.

sent by plans and issuers to enrollees and beneficiaries. Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe this is a usual and customary business practice. Plans and issuers routinely provide enrollees and beneficiaries with the Explanation of Benefit documents.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number. These paperwork burden estimates are summarized as follows:

Type of Review: Revision of an existing collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of Treasury.

Title: Disclosure Requirement for Patient Protections under the Affordable Care Act.

OMB Number: 1210–0142; 1545–2181.

Affected Public: Business or other for profit; not-for-profit institutions.

Total Respondents: 41,000.

Total Responses: 693,000.

Frequency of Response: One time.

Estimated Total Annual Burden Hours: 5,000 (Employee Benefits Security Administration); 5,000 (Internal Revenue Service).

Estimated Total Annual Burden Cost: \$5,500 (Employee Benefits Security Administration); \$5,500 (Internal Revenue Service).

4. ICR Regarding Affordable Care Act Internal Claims and Appeals and External Review

PHS Act section 2719 and these final regulations, require that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations under PHS Act section 2719.

The burden to comply with the DOL claims procedure regulations is accounted for under OMB control number 1210–0053, therefore it is not included here.

Paragraph (b)(2)(ii)(C) of the final regulations under PHS Act section 2719 adds an additional requirement that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered to be relied upon, or generated by the plan or issuer in

connection with the claim. The related hour burden is 1,100 hours and the related cost burden is \$1.1 million.

The June 2011 amendment to the interim final regulations required that plans and issuers must provide participants and beneficiaries who reside in a county where ten percent or more of the population residing in the county is literate only in the same non-English language with a one-sentence statement in all notices written in the applicable non-English language about the availability of language services. In addition to including the statement, plans and issuers are required to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request. Providing notice of the services and the translation services is estimated to have a cost burden of \$1 million annually.

Also, PHS Act section 2719 and these final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. Plans and issuers must provide to those conducting the external reviews required documents. There is an estimated 8,400 external appeals conducted annually. The related hour burden is 3,500 hours with an equivalent cost of \$193,700 and a cost burden of \$80,000 annually.

In total, the hour burden associated with claims, appeals, and external review is approximately 4,500 hours at an equivalent cost of \$244,800 annually. Because the burden is shared equally between the Department of Labor and the Department of the Treasury, each Department's share is 2,300 hours at an equivalent cost of \$122,400 annually.

In total, the cost burden is approximately \$2.2 million annually. Because the burden is shared equally between the Department of Labor and the Department of the Treasury, each Department's share is \$1.1 million annually.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.

The paperwork burden estimates are summarized as follows:

Type of Review: Revision.

Agency: Employee Benefit Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Affordable Care Act Internal Claims and Appeals and External

Review Disclosures for Non-Grandfathered Plans.

OMB Control Number: 1210–0144; 1545–2182.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 1,769,264.

Total Responses: 275,430.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours (three year average): 2,300 (Employee Benefits Security Administration); 2,300 (Internal Revenue Service).

Estimated Total Annual Cost Burden (three year average): \$1,143,000 (Employee Benefits Security Administration); \$1,143,000 (Internal Revenue Service).

B. Department of Health and Human Services

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. These final regulations contain ICRs that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized below in the Table below. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

As discussed above in the Department of Labor and Department of the Treasury PRA section, these final regulations contain a notice of grandfather status, rescissions notice, and patient protection disclosures requirement for issuers, and notice requirements related to internal claims and appeals and external review. These requirements are ICRs under the Paperwork Reduction Act. Each of these requirements is discussed in detail in the following sections. Estimated hourly labor rates are calculated using data from the 2013

National Occupational Employment Survey.¹⁶⁴

1. ICRs Regarding Affordable Care Act Notice of Grandfather Status (§§ 147.140(a)(2), 147.140(a)(3)(i), 147.140(a)(3)(ii))

a. Grandfathered Health Plan Disclosure

The final regulations provide model language for the grandfathered health plan disclosure that can be incorporated into existing plan documents. After plans first satisfied the grandfathered health plan disclosure requirement in 2011, any additional burden is expected to be negligible if a plan wants to maintain its grandfathered status in future years. It is also expected that the cost of removing the notice from plan documents as plans relinquish their grandfathered status would be minimal and therefore it is not estimated.

Issuers and multi-employer plans must also add a prominent disclosure in their group policies, certificates, or contracts of insurance that plan sponsors are required to notify the issuer if the contribution rate changes at any point during the plan year. This only affects issuers of fully insured group health plans and multi-employer plans and after this requirement is first satisfied, any additional burden in future years is expected to be negligible and is therefore not estimated.

Grandfathered plans will incur printing and material costs associated with the disclosure requirements. It is estimated that there will be approximately 47,500 grandfathered State and local governmental health plans with approximately 5.5 million policyholders¹⁶⁵ and approximately 1.4 million policyholders in the individual market with grandfathered coverage¹⁶⁶ issued by 430 issuers during 2015. Therefore, grandfathered plans and issuers in the individual markets will need to send approximately 6.9 million disclosures notifying plan participants and beneficiaries of their plans' status as a grandfathered health plan. We anticipate that the notice will require one-half of a page and five cents per page printing and material cost will be

incurred. We also assume that 38 percent of the notices will be delivered electronically. This results in a total annual cost burden of approximately \$106,000. The number of notices and cost burden are likely to be lower in subsequent years as more plans relinquish their grandfathered status. In the absence of data regarding how many plans will retain grandfathered status in subsequent years, we consider this estimate to be the upper limit for the number of notices and cost burden in future years.

b. Recordkeeping Requirement

It is assumed that most of the documents required to be retained to satisfy the recordkeeping requirement of these final regulations are already retained by plans for tax purposes, to satisfy ERISA's record retention and statute of limitations requirements, and for other business reasons. It was previously estimated that after the one-time cost related to record keeping requirement was incurred in 2011, costs in subsequent years will be negligible and, therefore, not estimated.

c. Grandfathered Plan Change in Carrier Disclosure

A group health plan that is changing health insurance issuers must provide to the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of § 147.140(g)(1) are exceeded.

The number of plans that might change carriers and thus be affected (7,400) is estimated by multiplying the estimated number of grandfathered plans (47,500) by the percent of plans shopping for a new carrier (58 percent) and the number of plans shopping for a new carrier that switched (27 percent).¹⁶⁷

Each employer will require about 2 minutes of clerical labor (at an hourly cost of approximately \$30) to send the information required for the disclosure (which is already retained under the recordkeeping requirement) electronically to the succeeding issuer. The total annual labor burden for all employers is estimated to be approximately 248 hours with an equivalent annual cost of approximately \$7,500. The cost of transmitting the information electronically to the succeeding issuer is negligible and,

therefore, not estimated. The number of disclosures and cost burden may be lower in subsequent years as more plans relinquish their grandfathered status. In the absence of data regarding how many plans will retain grandfathered status in subsequent years, we consider this estimate to be the upper limit for the burden in future years.

2. ICR Regarding Affordable Care Act Notice Relating to Rescissions (§ 147.128(a)(1))

This analysis assumes that rescissions only occur in the individual health insurance market, because rescissions in the group market are rare. It is estimated that there are approximately 430 issuers issuing 6.77 million policies in the individual market during a year. A report on rescissions found that 0.15 percent of policies were rescinded during the 2004 to 2008 time period. Based on these numbers, it is estimated that approximately 10,200 policies are rescinded during a year, which would result in approximately 10,200 notices being sent to affected policyholders, with 38 percent transmitted electronically and 62 percent mailed. It is estimated that each issuer will require 15 minutes of legal professional time (at approximately \$129.94 per hour) to prepare the notice and one minute per notice of clerical professional time (at approximately \$30.42 per hour) to distribute the notice to each policyholder. Assuming that the cost of electronic distribution is minimal, this results in an annual hour burden of approximately 212 hours with an equivalent annual cost of approximately \$17,160.

Issuers will incur cost to print and send the notices. We assume that the notice will require one page printing and material cost will be \$0.05 per page, mailing cost will be \$0.49 per notice, and 38 percent of the notices will be delivered electronically at minimal cost. Therefore, it is estimated that the cost burden associated with mailing the notices to approximately 6,300 affected policy holders will be approximately \$3,400.

3. ICR Regarding Affordable Care Act Patient Protection Disclosure Requirement (§ 147.138(a)(4))

b. Patient Protection Disclosure

In order to satisfy the patient protection disclosure requirement, State and local government plans and issuers in individual markets will need to notify policy holders of their plans policy in regards to designating a primary care physician and for obstetrical or gynecological visits and

¹⁶⁴ 2013 National Occupational Employment Survey, April 2014, Bureau of Labor Statistics, <http://www.bls.gov/news.release/pdf/ocwage.pdf>.

¹⁶⁵ The Department lacks data on the number of State and local plans that are grandfathered plans. The Kaiser "Employer Health Benefits Survey" has estimates for private employer plans. Those estimates are used here as a proxy. They report that 37 percent of plans are grandfather plans and 26 percent of covered employees are in those plans. <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/>.

¹⁶⁶ Estimate based on data from the McKinsey Center for US Health System Reform and Medical Loss Ratio submissions for 2013 reporting year.

¹⁶⁷ See Section 14. <http://kff.org/health-costs/report/2014-employer-health-benefits-survey/>.

will incur a one-time burden and cost to incorporate the notice into plan documents. State and local government plans that are currently not grandfathered and issuers in the individual market have already incurred the one-time cost to prepare and incorporate this notice in their existing plan documents. Only State and local government plans and individual market plans that relinquish their grandfathered status in subsequent years will become subject to this notice requirement and incur the one-time cost to prepare the notice.

There are an estimated 128,400 non-federal governmental plans and 430 health insurance issuers in the individual market. We estimate that five percent of non-federal governmental plans will relinquish their grandfathered status annually over the next three years and will therefore incur one-time costs to prepare the notice. Health insurance issuers in the individual market will also have five percent of their policies relinquish grandfathered status annually over the next three years. Data obtained from the 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 13 percent of plans have an HMO option and that 23 percent of plans offer a POS option. Thus, approximately 2,740 plans and issuers will produce notices each year.¹⁶⁸ While not all HMO and POS options require the designation of a primary care physician or a prior authorization or referral before a woman can visit an OB/GYN, the Department is unable to estimate this number. Therefore, this estimate should be considered an overestimate of the number of affected entities.

Each of these 2,740 plans and issuers will require a compensation and benefits manager to spend 10 minutes individualizing the model notice to fit the plan's specifications at an hourly rate of \$110.30. This results in approximately 457 hours of burden at an equivalent cost of \$50,400. Each plan will also require clerical staff to spend 5 minutes adding the notice to the plan's documents at an hourly rate of \$30.42. This results in approximately 228 hours of burden at an equivalent cost of \$7,000. The total annual burden associated with this requirement is 685 hours at an equivalent cost of \$57,000.

The Department assumes that only printing and material costs are associated with the disclosure

requirement, because the final regulations provide model language that can be incorporated into existing plan documents. The Department estimates that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically.

It is estimated that there are 27.9 million non-federal government plan policyholders and individual policyholders. As stated in the previous section, it is estimated that 5 percent of plans will relinquish their grandfathered status annually in the next three years. Data obtained from the 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 13 percent of covered workers in Government plans have an HMO option and that 8 percent of covered workers have a POS option. Data obtained from AHIP in 2009 finds that 1.93 percent of individual policyholders have an HMO options. Thus, it is estimated that plans will produce 228,000 notices each year, 38 percent of which will be sent electronically.¹⁶⁹ This results in a cost burden of approximately \$3,500.¹⁷⁰

c. Out-of-Network Emergency Services Disclosure

The final regulations require that a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is more restrictive than the copayment or coinsurance requirement that would apply if the services were provided in network. If State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, the a plan or issuer must provide an enrollee or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by an enrollee or beneficiary. This information should already be routinely included in the Explanation of Benefit documents sent by plans and issuers to enrollees and beneficiaries. Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe this is a usual and customary business practice. Plans and issuers routinely provide enrollees and beneficiaries with the Explanation of Benefit documents.

4. ICRs Regarding Affordable Care Act Internal Claims and Appeals and External Review (§§ 14.136 (b)(2)(ii), 147.136 (b)(2)(ii)(C), 147.136 (b)(3)(ii), 147.136 (b)(3)(ii)(C))

Paragraph (b)(2)(ii)(C) of the final regulations implementing PHS Act section 2719 provides that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim. The related hour burden is 773,800 hours and the related cost burden is \$115.2 million.

The June 2011 amendment to the interim final regulations under PHS Act section 2719 required that plans and issuers must provide participants and beneficiaries who reside in a county where ten percent or more of the population residing in the county is literate only in the same non-English language with a one-sentence statement in all notices written in the applicable non-English language, about the availability of language services. In addition to including the statement, plans and issuers are required to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request. Providing notice of the services and the translation services is estimated to have a cost burden of \$633,000 annually.

Also, PHS Act section 2719 and the final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. Plans and issuers must provide to those conducting the external reviews required documents. There is an estimated 2,100 external appeals conducted annually. The related hour burden is 150 hours with an equivalent cost of \$4,600 and a cost burden of \$5,400 annually.

In total, the burden associated with claims, appeals, and external review is approximately 774,000 hours at an equivalent cost of \$41,601,000 annually. The cost burden associated with claims, appeals, language translation, and external review is approximately \$115.8 million annually.

¹⁶⁸ 128,400 Governmental plans × 5% newly non-grandfathered plans × (13% HMOs + 23% POSs) + 430 issuers = approximately 2,700 affected plans and issuers.

¹⁶⁹ [21.1 million Government policyholders × 5% newly non-grandfathered plans × (13% in HMOs + 8% in POSs)] + [6.77 million individual policy holders × 5% newly non-grandfathered plans × 1.93% in HMOs] = approximately 228,000 notices.

¹⁷⁰ \$0.05 per page * 1/2 pages per notice * 228,000 notices * 62% = approximately \$3,500.

TABLE 2—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN (HHS)

	OMB Control No.	Number of respondents	Responses	Total annual burden (hours)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total costs (\$)
Grandfathered Plans Disclosure (§ 147.140(a)(2))	0938–1093	47,932	6,850,695	0	\$0	\$106,186	\$106,186
Grandfathered Plans Change in Carrier Disclosure (§ 147.140(a)(3)(i))	0938–1093	7,440	7,440	248	\$7,544	\$0	\$7,544
Rescissions Notice (§ 147.128(a)(1))	0938–1094	430	10,200	212	\$17,160	\$3,400	\$20,560
Patient Protection Disclosures (§ 147.138(a)(4))	0938–1094	2,741	228,086	685	\$57,341	\$3,535	\$60,876
Claims and Appeals External Review ((§ 147.136 (b)(2)(ii)(C), 147.136 (b)(3)(ii)(C))	0938–1098	95,500	399,151,000	773,996	\$41,601,000	\$115,827,000	\$157,428,000
Total		154,043	406,247,421	775,141			\$157,623,166

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities.

The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of “small entity.”) The Departments use as their measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed in detail in the “Need for Regulatory Action” section of this Regulatory Impact Analysis, these regulations are necessary to implement the following provisions: Affordable Care Act section 1251 (preservation of right to maintain existing coverage), and PHS Act sections 2704 (prohibition of preexisting condition exclusions), 2711 (no lifetime or annual limits), 2712 (prohibition on certain rescissions), 2714 (extension of dependent coverage), 2719 (internal appeals and external review process), and 2719A (patient protections). In response to the 2010 interim final regulations, the Departments received many comments that relate to early implementation issues and addressed many of these issues through sub-regulatory guidance. The Departments also held meetings with stakeholders, including small entities affected by the rules. After

consideration of comments and stakeholder input received in response to the interim final regulations, the Departments are issuing these final regulations.

The Regulatory Flexibility Act requires agencies to assess and consider the direct economic impacts that regulations impose on small entities. The primary economic effects of these final regulations are indirect, because they result in transfers between individuals covered by health insurance. While these transfers could be significant, they do not impose direct effects on the regulated small entities for purposes of the RFA.

Most of the direct effects of the final regulations are associated with their disclosure requirements. As discussed below and in the Paperwork Reduction Act section above, these disclosure requirements do not have a significant economic impact. Therefore, pursuant to section 605(b) of the RFA, the Departments hereby certify that these final regulations are not likely to have a significant economic impact on a substantial number of small entities. The Departments’ basis for this determination and their estimate of small entities affected by these final regulations is discussed below.

A. Affected Small Entities

There are several different types of small entities affected by these final regulations. For issuers and third party administrators, a small business is one that has total premium revenue of \$38.5 million or less. The Departments continue to consider a small plan to be an employee benefit plan with fewer than 100 participants.¹⁷¹ Further, while some large employers may have small

plans, in general small employers maintain most small plans. Thus, the Departments believe that assessing the impact of this final rule on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*).

Based on data from MLR annual report submissions for the 2013 MLR reporting year, approximately 141 out of 500 issuers of health insurance coverage nationwide had total premium revenue of \$38.5 million or less.¹⁷² This estimate may overstate the actual number of small health insurance companies that may be affected, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding \$38.5 million.

As discussed previously in the RIA, there are an estimated 2.3 million ERISA-covered plans and 128,400 State and local governmental health plans that may have experienced an increase in costs related to the provisions of these final rules. Ninety-seven percent of these plans are provided by small entities and have incurred costs related to the provisions of these final regulations.

¹⁷¹ The basis for this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants.

¹⁷² U. S. Small Business Administration, “Table of Small Business Size Standards Matched to North American Industry Classification System Codes”, July 14, 2014.

B. Direct Impacts of Final Rules on Small Entities

1. Affordable Care Act Section 1251, Preservation of Right To Maintain Existing Coverage (26 CFR 54.9815–1251, 29 CFR 2590.715–1251, 45 CFR 147.140)

The direct impacts of this provision on affected small entities are primarily associated with notices requirements. Specifically, the final regulations require affected plans to maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents that are necessary to verify, explain or clarify status as a grandfathered health plan (the “recordkeeping requirement”). The plan must make such records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official. The Departments believe this requirement imposes a minimal burden on small entities, because they should maintain such records in the usual and customary course of their business operations following standard business procedures.

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 to consumers. The Departments believe the costs associated with this disclosure are minimal, because a model statement is provided in the final rule and that statement can be provided in any summary of benefits that already is being provided to consumers.

Finally, if a grandfathered group health plan switches issuers and intends to maintain its status as a grandfathered plan, it must provide to the new health insurance issuer with documentation of plan terms under the prior health coverage sufficient for it to determine whether a change causing a cessation of grandfathered health plan status has occurred. This requirement also imposes a minimal burden on affected small entities, because the documents should be maintain in the ordinary course of the plan’s business operations, and the only additional cost would be incurred to prepare the documentation for mailing and associated material and printing cost, which are estimated to total approximately \$8.

1. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108)

The direct impacts of this rule on the regulated small entities is limited as the removal of preexisting condition exclusions primarily operates through the pricing of insurance products, which are paid by plan participants. Small businesses will be impacted when they pay for part of the health insurance premium. The Departments have not been able to estimate this effect separately from the effect on premiums brought about by the other the Affordable Care Act changes.

2. PHS Act Section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815–2711, 29 CFR 2590.715–2711, 45 CFR 147.126)

The direct impacts of this rule on the regulated small entities were primarily limited to an initial notice sent shortly after the issuance of the interim final regulations requiring plans to notify participants that had lost coverage due to reaching the lifetime limit of the new coverage option. This notice requirement is no longer in effect as the statute now bans all annual and life time limits, so there are no individuals losing coverage that need to be notified. To the extent premiums increase and employers contribute part of the premiums, or plans are self-insured with payments from the employers general assets there could be direct effects on employers, but for most employers those effects are small.

3. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.128)

PHS Act Section 2712 and the final regulations prohibit group health plans and health insurance issuers that offer group or individual health insurance coverage generally from rescinding coverage under the plan, policy, certificate, or contract of insurance from the individual covered under the plan or coverage unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. The final regulations provide that a group health plan or a health insurance issuer offering group health insurance coverage must provide at least 30 days advance notice to an individual before coverage may be rescinded. The Departments believe that rescissions are

rare in the group market and that small group health plans are affected by rescissions more than large group health plans.

The Departments estimate¹⁷³ that 15 minutes of legal professional time at \$129.94 per hour¹⁷⁴ would be required by the insurers of the policies to prepare the notice, and one minute per notice of clerical professional time at \$30.42 per hour¹⁷⁵ would be required to distribute the paper notices. The Departments believe the costs of electronic transmission would be de minimis. This leads to an estimate of less than \$40 per rescission notice, which the Departments do not believe is significant.

4. PHS Act Section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120)

The direct impacts of this rule on the regulated small entities were primarily limited to an initial notice sent shortly after the issuance of the interim final regulations requiring plans to notify participants of the new coverage option. To the extent premiums increase and employers contribute part of the premiums, or plans are self-insured with payments from the employers general assets there could be direct effects on employers, but for most employers those effects are small.

5. PHS Act Section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, 45 CFR 147.136)

Not all potentially affected individuals will be affected equally by these final regulations. Sponsors of ERISA-covered group health plans were required to implement an internal

¹⁷³ The Department’s estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: Mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/pdf/ocwage.pdf>); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/ecec.t02.htm>); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 <http://www.bls.gov/news.release/eci.nr0.htm>).

¹⁷⁴ Legal Professional (23–1011): \$63.46 (2013 BLS Wage rate)/0.69 (ECEC ratio) * 1.35 (Overhead Load Factor) * 1.023 (Inflation rate) ^2 (Inflated 2 years from base year) = \$129.94.

¹⁷⁵ Secretaries, Except Legal, Medical, and Executive (43–6014): \$16.35 (2013 BLS Wage rate)/0.675 (ECEC ratio) * 1.2 (Overhead Load Factor) * 1.023 (Inflation rate) ^2 (Inflated 2 years from base year) = \$30.42

appeals process that complied with the DOL claims procedure regulation before the Affordable Care Act's enactment, and the Departments also understand that many non-Federal governmental plans and church plans that are not subject to ERISA implement internal claims and appeals processes that comply with the DOL claims procedure regulation.

These final regulations will have the largest impact on individuals covered in the individual health insurance market, because with the issuance of the final regulation, these issuers were required to comply with the DOL claims procedure regulation for internal claims and appeals as well as the additional standards added by the Secretary of the Department of Health and Human Services in paragraph (b)(3) of the final regulations under PHS Act section 2719 that are in some cases more protective than the ERISA standard.

Using estimates calculated for the Paperwork Reduction Act it is estimated that there will be an average costs of 40 cents per notice that is required to be sent related to the internal claims and appeals.

On the external appeals side, before the enactment of the Affordable Care Act, issuers offering coverage in the group and individual health insurance market were already required to comply with State external review laws. At that time, all States except Alabama, Mississippi, Nebraska, North Dakota, South Dakota, and Wyoming had external review laws, and thirteen States had external review laws that apply only to certain market segments (for example, managed care or HMOs). Currently, all States except, Alabama, Alaska, Florida, Georgia, Pennsylvania, and Wisconsin have State external review laws that satisfy these requirements. These six states that do not meet the requirements, must use the HHS administered process or must contract with accredited independent review organizations to review external appeals on their behalf.¹⁷⁶

Individuals participating in ERISA-covered self-insured group health plans will be among those most affected by the external review requirements contained in these final regulations, because the preemption provisions of ERISA prevent a State's external review process from applying directly to an ERISA-covered self-insured plan. These plans will now be required to comply with the Federal external review process set forth in these final regulations.

¹⁷⁶ https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.

As discussed in the Regulatory Impact Section above an estimate for the average cost for an external appeal is \$665. This cost would be incurred by plans or issuers. It is also estimated above that there is on average only 1.3 external appeals per 10,000 covered lives. The Departments believe such costs are minimal for purpose of the RFA, because most small entities will have no external appeals in a given year.

6. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138)

PHS Act section 2719A imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of health care professionals. When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; (2) obtain obstetrical or gynecological care without prior authorization; or (3) coverage of emergency services. Accordingly, these final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscriber) of these rights when applicable. Model language is provided in these final regulations. The notice must be provided 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, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

The Departments assume that this provision will primarily affect Health Maintenance Organizations and Point-of-Service type arrangements. The Department believes that insignificant costs are associated with this notice, because a model notice is provided in the final rule, and it can be distributed with existing plan documents.

The Departments estimate that each plan or issuer would require a compensation and benefits manager¹⁷⁷

¹⁷⁷ The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: Mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/pdf/ocwage.pdf>); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics <http://www.bls.gov/news.release/eccc.t02.htm>); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of

to spend 10 minutes individualizing the model notice provided by the Departments to fit the plan's specifications at an hourly rate of \$110.30.¹⁷⁸ This results in a cost of approximately \$21 in the first year. The cost per participant to receive the notice would be less than five cents per paper notice as the notice would be included in existing documents.

VI. Unfunded Mandates Reform Act—Department of Labor and Department of Health and Human Services

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by State, local or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars updated annually for inflation. In 2015, that threshold level is approximately \$144 million. These final regulations include a Federal mandate that may result in expenditures by State, local, or Tribal governments. Specifically, these final regulations include requirements regarding minimum consumer protection standards that a State external review process must include to qualify as an applicable State external review process under PHS Act section 2719(b)(1). However, we conclude that these costs would not exceed the \$144 million threshold. Thus, the Departments of Labor and HHS conclude that these final regulations would not impose an unfunded mandate on State, local or Tribal governments or the private sector. Regardless, consistent with the policy embodied in UMRA, the final requirements described in this notice of final rulemaking has been designed to be the least burdensome alternative for State, Local and Tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

VII. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific

compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 <http://www.bls.gov/news.release/eci.nr0.htm>).

¹⁷⁸ Compensation and Benefits Manager (11–3041): \$53.87 (2013 BLS Wage rate)/0.69 (ECEC ratio) * 1.35 (Overhead Load Factor) * 1.023 (Inflation rate) ^2 (Inflated 2 years from base year) = \$110.30.

criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments of Labor’s and HHS’ view, these final regulations have federalism implications because they would have direct effects on the States, the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government. Under these final regulations, group health plans and health insurance issuers offering group or individual health insurance coverage, including non-federal governmental plans as defined in section 2791 of the PHS Act, would be required to follow the Federal standards developed under Affordable Care Act section 1251 and PHS Act sections 2704, 2711, 2712, 2714, 2719 and 2719A, as added by the Affordable Care Act. However, in the Departments’ view, the federalism implications of these final regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal standards.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements in title XXVII of the PHS Act (including those added by the Affordable Care Act) are not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of

a requirement of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the “narrowest” preemption of State laws (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018).

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments of Labor and HHS have engaged in efforts to consult with and work cooperatively with affected States, including consulting with, and attending conferences of, the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments of Labor and HHS will act in a similar fashion in enforcing the Affordable Care Act.

Throughout the process of developing these final regulations, to the extent feasible within the applicable preemption provisions, the Departments of Labor and HHS have attempted to balance the States’ interests in regulating health insurance issuers, and Congress’ intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments of Labor’s and HHS’ view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this final rule, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached final rules in a meaningful and timely manner.

VIII. Special Analyses—Department of the Treasury

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure

Act (5 U.S.C. chapter 5) does not apply to these final regulations. For a discussion of the impact of this final rule on small entities, please see section V.B. of this preamble. Pursuant to section 7805(f) of the Code, this notice of final rulemaking has been submitted to the Small Business Administration for comment on its impact on small business.

IX. Congressional Review Act

These final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller General for review.

X. Statutory Authority

The Department of the Treasury final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1135, and 1191c; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Parts 144 and 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

requirements, and State regulation of health insurance.

John Dalrymple,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: October 27, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 6 day of November 2015.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 15, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 22, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

For the reasons stated in the preamble, the Internal Revenue Service amends Part 54 as set forth below:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding entries for §§ 54.9815–1251, 54.9815–2704, 54.9815–2711, 54.9815–2712, 54.9815–2714, 54.9815–2719, and 54.9815–2719A in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9815–1251 also issued under 26 U.S.C. 9833.

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Section 54.9815–2704 also issued under 26 U.S.C. 9833.

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Section 54.9815–2711 also issued under 26 U.S.C. 9833.

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Section 54.9815–2712 also issued under 26 U.S.C. 9833.

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Section 54.9815–2714 also issued under 26 U.S.C. 9833.

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Section 54.9815–2719 also issued under 26 U.S.C. 9833.

Section 54.9815–2719A also issued under 26 U.S.C. 9833.

■ **Par. 2.** Section 54.9801–2 is amended by revising the introductory text and the definition of “preexisting condition exclusion” to read as follows:

§ 54.9801–2 Definitions.

Unless otherwise provided, the definitions in this section govern in

applying the provisions of sections 9801 through 9815 and 9831 through 9833.

* * * * *

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

* * * * *

■ **Par. 3.** Section 54.9801–3 is amended by revising the section heading and paragraph (a)(1) to read as follows:

§ 54.9801–3 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion defined*—(1) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning of § 54.9801–2.

* * * * *

■ **Par. 4.** Section 54.9815–1251 is added to read as follows:

§ 54.9815–1251 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 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 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 paragraph (b)(2)(ii)(C) of this section, 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, see 45 CFR 147.140(c), which provides that 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 beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans—In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of

the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. 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)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, 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)(3)(i) of this section (that is, \$5 times medical inflation, plus \$5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802(d)) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the

employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802(d)) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(C) *Special rules regarding decreases in contribution rates.* An insured group health plan (or a multiemployer plan) that is a grandfathered health plan will not cease to be a grandfathered health plan based on a change in the employer contribution rate unless the issuer (or multiemployer plan) knows, or should know, of the change, provided:

(1) Upon renewal (or, in the case of a multiemployer plan, before the start of a new plan year), the issuer (or multiemployer plan) requires relevant employers, employee organizations, or plan sponsors, as applicable, to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer, or multiemployer plan, does not already have it); and

(2) The relevant policies, certificates, contracts of insurance, or plan documents disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year.

(D) *Application to plans with multi-tiered coverage structures.* The standards for employer contributions in this paragraph (g)(1)(v) apply on a tier-by-tier basis. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.*, self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.*, at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be

analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage would not cause the plan to lose grandfather status.

(E) *Group health plans with fixed-dollar employee contributions or no employee contributions.* A group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan solely because the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage.

(vi) *Changes in annual limits—(A) Addition of an annual limit.* A group health plan, or group 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 § 54.9815–2711, which prohibits all annual dollar limits on essential health benefits for plan years beginning on or after January 1, 2014).

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* A group health plan, or group 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 § 54.9815–2711, which prohibits all annual dollar limits on essential health benefits for plan 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 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 § 54.9815–2711, which prohibits all annual dollar limits on essential health benefits for plan 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) *Definitions—(i) Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted)

published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

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

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to \$40. Within the 12-month period before the \$40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3*, the increase in the copayment from \$30 to \$40, expressed as a percentage, is 33.33% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). The maximum percentage increase permitted is 37.69% ($0.2269 = 22.69\%$; $22.69\% + 15\% = 37.69\%$). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3*, except the grandfathered health plan subsequently increases the \$40 copayment requirement to \$45 for a later plan year. Within the 12-month period before the \$45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4*, the increase in the copayment from \$30 (the copayment that was in effect on March 23, 2010) to \$45, expressed as a percentage, is 50% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% ($0.2527 = 25.27\%$; $25.27\% + 15\% = 40.27\%$), or \$6.26 ($\$5 \times 0.2527 = \1.26 ; $\$1.26 + \$5 = \$6.26$).

Because 50% exceeds 40.27% and \$15 exceeds \$6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment of \$10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$15. Within the 12-month period before the \$15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(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) of this section is the greater of the maximum percentage increase of 22.20% ($0.0720 = 7.20\%$; $7.20\% + 15\% = 22.20\%$), or \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to \$5.36.

Example 6. (i) *Facts.* The same facts as *Example 5*, except on March 23, 2010, the grandfathered health plan has no copayment (\$0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$5.

(ii) *Conclusion.* In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of \$5.36. Thus, the \$5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of \$5000 for self-only coverage and \$12,000 for family coverage. The required employee contribution for the coverage is \$1000 for self-only coverage and \$4000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ($(5000 - 1000)/5000$) for self-only coverage and 67% ($(12,000 - 4000)/12,000$) for family coverage. For a subsequent plan year, the COBRA premium is \$6000 for self-only coverage and \$15,000 for family coverage. The employee contributions for that plan year are \$1200 for self-only coverage and \$5000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ($(6000 - 1200)/6000$) for self-only coverage and 67% ($(15,000 - 5000)/15,000$) for family coverage.

(ii) *Conclusion.* In this *Example 8*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) Facts. A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) Conclusion. In this *Example 9*, the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

§ 54.9815–1251T [Removed]

■ **Par. 5.** Section 54.9815–1251T is removed.

■ **Par. 6.** Section 54.9815–2704 is added to read as follows:

§ 54.9815–2704 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions.* A group health plan, or a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 54.9801–2).

(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 § 54.9801–3(a)(2)):

Example 1. (i) Facts. A group health plan provides benefits solely through an insurance policy offered by Issuer *P*. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N*. *N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

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

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

(ii) Conclusion. See *Example 2* in 45 CFR 147.108(a)(2) 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. Therefore, such an exclusion is prohibited.

(c) *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, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2704T [Removed]

■ **Par. 7.** Section 54.9815–2704T is removed.

■ **Par. 8** Section 54.9815–2711 is added to read as follows:

§ 54.9815–2711 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 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 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 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 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 this purpose, 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 consistent with one of the three Federal Employees Health Benefit Program (FEHBP) options as defined by 45 CFR 156.100(a)(3) or one of the base-benchmark plans selected by a State or applied by default pursuant to 45 CFR 156.100.

(d) *Special rule for health reimbursement arrangements (HRAs) and other account-based plans—(1) In general.* If an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based plan are limited does not mean that the HRA or other account-based plan fails to meet the requirements of paragraph (a)(2) of this section. Similarly, if an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in PHS Act section 2713 and section 54.9815–2713(a)(1), the HRA or other account-based plan will not fail to meet the requirements of PHS Act section 2713 and § 54.9815–2713(a)(1).

(2) *Integration requirements.* An HRA or other account-based plan is integrated with a group health plan for purposes of paragraph (a)(2) of this section if it meets the requirements under either the integration method set forth in paragraph (d)(2)(i) of this section or the integration method set forth in paragraph (d)(2)(ii) of this section. Integration does not require that the HRA (or other account-based plan) and the 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. The term “excepted benefits” is used throughout the integration methods; for a definition of the term “excepted benefits” see Code section 9832(c), ERISA section 733(c), and PHS Act section 2791(c).

(i) *Integration Method: Minimum value not required.* An HRA or other

account-based plan is integrated with another group health plan for purposes of this paragraph if:

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

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan (other than the HRA or other account-based 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 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 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 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 (as defined under section 213(d) of the Code) that does 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 plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

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

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

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a 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 plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based 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 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 plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(3) *Forfeiture.* For purpose 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 this purpose coverage under an HRA or other account-based 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 plan. This means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based plan may not be used to reimburse or pay medical expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *No integration with individual market coverage.* A group health plan, including an HRA or other account-based plan, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of paragraph (a)(2) of this section (or for purposes of

the requirements of PHS Act section 2713).

(5) *Integration with Medicare parts 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 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 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 plan is actually enrolled Medicare part B or D;

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

(iv) The HRA or other account-based plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Account-based plan.* An account-based plan for purposes of this section is an employer-provided group health plan that provides reimbursements of medical expenses other than individual market policy premiums with the reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based plan.

(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, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2711T [Removed]

■ **Par. 9.** Section 54.9815–2711T is removed.

■ **Par. 10.** Section 54.9815–2712 is added to read as follows:

§ 54.9815–2712 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group 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 health insurance coverage, must provide at least 30 days advance written notice to each participant who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of 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 45 CFR 155.430 (other than under paragraph (b)(2)(iii)).

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

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. 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 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 interim final regulations promulgated by the Department of Labor at 29 CFR part

2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2712T [Removed]

■ **Par. 11.** Section 54.9815–2712T is removed.

■ **Par. 12.** Section 54.9815–2714 is added to read as follows:

§ 54.9815–2714 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group 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. 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 any other person); residency with the participant 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). For an individual not described in 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 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 interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2714T [Removed]

■ **Par. 13.** Section 54.9815–2714T is removed.

■ **Par. 14.** Section 54.9815–2719 is added to read as follows:

§ 54.9815–2719 Internal claims and appeals and external review processes.

(a) *Scope and definitions—(1) Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 54.9815–1251. 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.

(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 § 54.9815–2712(a)(2) (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 health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health

insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an “adverse benefit determination” includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 54.9815–2712.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan’s benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(1) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan’s benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that

the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(1) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(3) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan’s or issuer’s standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(4) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(5) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes—(1)* In the case of a plan or issuer that fails to 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.

(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 health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section); or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed \$25; it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review; it must be waived if payment of the fee would impose an undue financial hardship; and the annual limit on filing fees for any claimant within a single plan year must not exceed \$75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a \$500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a

notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan

or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially

similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process*. A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in

connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope—(i) In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812, 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 or beneficiary 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)); and

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

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

Example 1. (i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual A seeks coverage for

a 31st physical therapy visit. A's health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, A receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1*, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual B seeks coverage for a specialized medical procedure from an out-of-network provider because B believes that the procedure cannot be effectively provided in network. B receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2*, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

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

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the

plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

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

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

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

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

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

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

period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

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

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

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

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

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

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

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

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

the IRO must notify the claimant and the plan.

(4) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(5) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(i) The claimant's medical records;

(ii) The attending health care professional's recommendation;

(iii) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(iv) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(v) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(vi) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(vii) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(6) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(7) The assigned IRO's written notice of the final external review decision must contain the following:

(i) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(ii) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(iii) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(iv) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(v) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(vi) A statement that judicial review may be available to the claimant; and

(vii) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(viii) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records

available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(iv) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer

will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section 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 health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements.* (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes

answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

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

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

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

(g) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan 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 interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ **Par. 15.** Section 54.9815–2719A is added to read as follows:

§ 54.9815–2719A 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 health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant 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 health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary 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 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 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 or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant 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 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 or beneficiary 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 or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant 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 or beneficiary 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.

(i) *Timing.* 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.

(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 or beneficiaries, 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 or beneficiary 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 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 or beneficiary for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant or beneficiary if the services were provided in-network. However, a participant or beneficiary 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 or beneficiary. 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 or beneficiary. 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 or beneficiary. 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 or beneficiary.

(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 or beneficiary 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 or beneficiary 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 or beneficiary.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1*, the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2*, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept \$85, two have agreed to accept \$100, two have agreed to accept \$110, three have agreed to accept \$120, and one has agreed to accept \$150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3*, the values taken into account in determining the

median are \$85, \$100, \$100, \$110, \$110, \$120, \$120, \$120, and \$150. Therefore, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of \$110 (\$88).

Example 4. (i) *Facts.* Same facts as *Example 3*. Subsequently, the plan adds another provider to its network, who has agreed to accept \$150 for the emergency service.

(ii) *Conclusion.* In this *Example 4*, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of \$115 (\$92).

Example 5. (i) *Facts.* Same facts as *Example 4*. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is \$80.

(ii) *Conclusion.* In this *Example 5*, the plan is responsible for paying \$92.80, 80% of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80% of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—\$116—excluding the in-network 20% coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5*. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6*, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

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

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

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

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

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years 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 interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2719AT [Removed]

■ **Par. 16.** Section 54.9815–2719AT is removed.

§ 54.9815–2719T [Removed]

■ **Par. 17.** Section 54.9815–2719T is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Employee Benefits Security Administration adopts as final the interim final rules amending 29 CFR part 2590, which were published in the **Federal Register** on May 13, 2010 (75 FR 27122), June 17, 2010 (75 FR 34538), June 28, 2010 (75 FR 37188), and November 17, 2010 (75 FR 70114) with the following changes as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 18. The authority citation for Part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 19. Section 2590.701–2 is amended by revising the definition of “preexisting condition exclusion” to read as follows:

§ 2590.701–2 Definitions.

* * * * *

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

part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

■ 20. Section 2590.701–3 is amended by revising paragraph (a)(1) to read as follows:

§ 2590.701–3 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion defined*—(1) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning of § 2590.701–2.

* * * * *

■ 21. Section 2590.715–1251 revised to read as follows:

§ 2590.715–1251 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 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 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, *see* 45 CFR 147.140(c), which provides that 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 beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group

health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans*—*In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. 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)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, 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)(3)(i) of this section (that is, \$5 times medical inflation, plus \$5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 2590.702(d)) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 2590.702(d)) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(C) *Special rules regarding decreases in contribution rates.* An insured group health plan (or a multiemployer plan) that is a grandfathered health plan will not cease to be a grandfathered health plan based on a change in the employer contribution rate unless the issuer (or multiemployer plan) knows, or should know, of the change, provided:

(1) Upon renewal (or, in the case of a multiemployer plan, before the start of a new plan year), the issuer (or multiemployer plan) requires relevant employers, employee organizations, or plan sponsors, as applicable, to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer, or multiemployer plan, does not already have it); and

(2) The relevant policies, certificates, contracts of insurance, or plan

documents disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year.

(D) *Application to plans with multi-tiered coverage structures.* The standards for employer contributions in this paragraph (g)(1)(v) apply on a tier-by-tier basis. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.*, self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.*, at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage would not cause the plan to lose grandfather status.

(E) *Group health plans with fixed-dollar employee contributions or no employee contributions.* A group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan solely because the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group 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 § 2590.715–2711, which prohibits all annual dollar limits on essential health

benefits for plan years beginning on or after January 1, 2014).

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* A group health plan, or group 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 § 2590.715–2711, which prohibits all annual dollar limits on essential health benefits for plan 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 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 § 2590.715–2711, which prohibits all annual dollar limits on essential health benefits for plan 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) *Definitions*—(i) *Medical inflation defined*. For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined*. For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined*. For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage*. The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA

continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula*. The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

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

Example 1. (i) *Facts*. On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion*. In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts*. Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion*. In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts*. On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to \$40. Within the 12-month period before the \$40 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 475.

(ii) *Conclusion*. In this *Example 3*, the increase in the copayment from \$30 to \$40, expressed as a percentage, is 33.33% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). The maximum percentage increase permitted is 37.69% ($0.2269 = 22.69\%$; $22.69\% + 15\% = 37.69\%$). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts*. Same facts as *Example 3*, except the grandfathered health plan subsequently increases the \$40 copayment requirement to \$45 for a later plan year. Within the 12-month period before the \$45 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 485.

(ii) *Conclusion*. In this *Example 4*, the increase in the copayment from \$30 (the copayment that was in effect on March 23, 2010) to \$45, expressed as a percentage, is 50% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% ($0.2527 = 25.27\%$; $25.27\% + 15\% = 40.27\%$), or \$6.26 ($\$5 \times 0.2527 = \1.26 ; $\$1.26 + \$5 = \$6.26$). Because 50% exceeds 40.27% and \$15 exceeds \$6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts*. On March 23, 2010, a grandfathered health plan has a copayment of \$10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$15. Within the 12-month period before the \$15 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) *Conclusion*. In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(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) of this section is the greater of the maximum percentage increase of 22.20% ($0.0720 = 7.20\%$; $7.20\% + 15\% = 22.20\%$), or \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to \$5.36.

Example 6. (i) *Facts*. The same facts as *Example 5*, except on March 23, 2010, the grandfathered health plan has no copayment (\$0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$5.

(ii) *Conclusion*. In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of \$5.36. Thus, the \$5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts*. On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of \$5,000 for self-only coverage and \$12,000 for family coverage. The required employee contribution for the coverage is \$1,000 for self-only coverage and \$4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% $((5,000 - 1,000)/5,000)$ for self-only coverage and 67% $((12,000 - 4,000)/12,000)$ for family coverage. For a subsequent plan year, the COBRA premium is \$6,000 for self-only coverage and \$15,000 for family coverage. The employee contributions for that plan year are \$1,200 for self-only coverage and \$5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% $((6,000 - 1,200)/6,000)$ for self-only coverage and 67% $((15,000 - 5,000)/15,000)$ for family coverage.

(ii) *Conclusion.* In this *Example 8*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 9*, the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the (rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

■ 22. Section 2590.715–2704 is revised to read as follows:

§ 2590.715–2704 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions.* A group health plan, or a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701–2).

(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 § 2590.701–3(a)(2)):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P*. At the expiration of the policy, the plan switches coverage to

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

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

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

(ii) *Conclusion.* See *Example 2* in 45 CFR 147.108(a)(2) 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. Therefore, such an exclusion is prohibited.

(c) *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, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ 23. Section 2590.715–2711 is revised to read as follows:

§ 2590.715–2711 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 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 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 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 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 this purpose, 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 consistent with one of the three Federal Employees Health Benefit Program (FEHBP) options as defined by 45 CFR 156.100(a)(3) or one of the base-benchmark plans selected by a State or applied by default pursuant to 45 CFR 156.100.

(d) *Special rule for health reimbursement arrangements (HRAs) and other account-based plans—(1) In general.* If an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based plan are limited does not mean that the HRA or other account-based plan fails to meet the requirements of paragraph (a)(2) of this section. Similarly, if an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in PHS Act section 2713 and § 2590.715–2713(a)(1), the HRA or other account-based plan will not fail to meet the requirements of PHS Act section 2713 and § 2590.715–2713(a)(1).

(2) *Integration requirements.* An HRA or other account-based plan is integrated with a group health plan for purposes of paragraph (a)(2) of this section if it meets the requirements under either the integration method set forth in paragraph (d)(2)(i) of this section or the integration method set forth in paragraph (d)(2)(ii) of this section. Integration does not require that the HRA (or other account-based plan) and the 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. The term “excepted benefits” is used throughout the integration methods; for a definition of the term “excepted benefits” see Internal Revenue Code section 9832(c), ERISA section 733(c), and PHS Act section 2791(c).

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

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

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan (other than the HRA or other account-based 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 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 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 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 (as defined under section 213(d) of the Internal Revenue Code) that does 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 plan, an employee (or former employee) is permitted to permanently opt out of and waive future

reimbursements from the HRA or other account-based plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

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

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

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Internal Revenue Code (and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based 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 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 plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(3) *Forfeiture.* For purpose 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 this purpose coverage under an HRA or other account-based 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 plan. This means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based plan may not be used to reimburse or pay medical expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *No integration with individual market coverage.* A group health plan, including an HRA or other account-based plan, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of paragraph (a)(2) of this section (or for purposes of the requirements of PHS Act section 2713).

(5) *Integration with Medicare parts 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 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 (d)(2)(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 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 plan is actually enrolled Medicare part B or D;

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

(iv) The HRA or other account-based plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Account-based plan.* An account-based plan for purposes of this section is an employer-provided group health plan that provides reimbursements of medical expenses other than individual market policy premiums with the

reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based plan.

(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, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

24. Section 2590.715–2712 is revised to read as follows:

§ 2590.715–2712 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group 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 health insurance coverage, must provide at least 30 days advance written notice to each participant who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of 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 45 CFR 155.430 (other than under paragraph (b)(2)(iii)).

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

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. 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 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 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

25. Section 2590.715–2714 is revised to read as follows:

§ 2590.715–2714 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group 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. 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 any other person); residency with the participant 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 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 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ 26. Section 2590.715–2719 is revised to read as follows:

§ 2590.715–2719 Internal claims and appeals and external review processes.

(a) *Scope and definitions—(1) Scope.*

This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 2590.715–1251. 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.

(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 § 2590.715–2712(a)(2) (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 health insurance

coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an “adverse benefit determination” includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 2590.715–2712.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan’s benefit determination (whether adverse or not) as soon as possible, taking into

account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(1) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan’s benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are

adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(1) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(3) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan’s or issuer’s standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(4) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(5) The plan and issuer must disclose the availability of, and contact

information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*—(1) In the case of a plan or issuer that fails to 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.

(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 health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of

this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed \$25; it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review; it must be waived if payment of the fee would impose an undue financial hardship; and the annual limit on filing

fees for any claimant within a single plan year must not exceed \$75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a \$500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review,

and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process*. A plan or issuer not subject to an applicable State external review process

under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope—(i) In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812, 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 or beneficiary 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)); and

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

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

Example 1. (i) Facts. A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1*, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) Facts. A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2*, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(2) *External review process standards.* The Federal external review process

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

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

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

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

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

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

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

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone

number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization.* (A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

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

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

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

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

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

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

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

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

review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(4) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(5) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(i) The claimant's medical records;

(ii) The attending health care professional's recommendation;

(iii) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(iv) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(v) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government,

national or professional medical societies, boards, and associations;

(vi) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(vii) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(6) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(7) The assigned IRO's written notice of the final external review decision must contain the following:

(i) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(ii) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(iii) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(iv) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(v) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(vi) A statement that judicial review may be available to the claimant; and

(vii) Current contact information, including phone number, for any applicable office of health insurance

consumer assistance or ombudsman established under PHS Act section 2793.

(viii) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(iv) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph

(d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section 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 health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this

section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements—(i)* The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

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

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

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

(g) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan 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 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ 27. Section 2590.715–2719A is revised to read as follows:

§ 2590.715–2719A 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 health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who

is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant 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 health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary 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 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 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 or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant 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 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 or beneficiary 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 or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant 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 or beneficiary 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.* 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.

(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 or beneficiaries, 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 or beneficiary 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 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 or beneficiary for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant or beneficiary if the services were provided in-network. However, a participant or beneficiary 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 or beneficiary. 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 or beneficiary. 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 or beneficiary. 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 or beneficiary.

(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 or beneficiary 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 or beneficiary 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 or beneficiary.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1*, the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2*, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept \$85, two have agreed to accept \$100, two have agreed to accept \$110, three have agreed to accept \$120, and one has agreed to accept \$150. Under the agreement,

the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3*, the values taken into account in determining the median are \$85, \$100, \$100, \$110, \$110, \$120, \$120, \$120, and \$150. Therefore, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of \$110 (\$88).

Example 4. (i) *Facts.* Same facts as *Example 3*. Subsequently, the plan adds another provider to its network, who has agreed to accept \$150 for the emergency service.

(ii) *Conclusion.* In this *Example 4*, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of \$115 (\$92).

Example 5. (i) *Facts.* Same facts as *Example 4*. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is \$80.

(ii) *Conclusion.* In this *Example 5*, the plan is responsible for paying \$92.80, 80% of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80% of \$115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—\$116—excluding the in-network 20% coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5*. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6*, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the

higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

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

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

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

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

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years 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 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Chapter I

For the reasons stated in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR parts 144, 146 and 147, which were published in the **Federal Register** on May 13, 2010 (75 FR 27122), June 17, 2010 (75 FR 34538), June 28, 2010 (75 FR 37188), and November 17, 2010 (75 FR 70114) with the following changes as set forth below:

PART 144—REQUIREMENTS RELATED TO HEALTH INSURANCE

■ 28. The authority citation for part 144 continues to read as follows:

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

■ 29. Section 144.103 is amended by revising the definition of “preexisting condition exclusion” to read as follows:

§ 144.103 Definitions.

* * * * *

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

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 30. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

■ 31. Section 146.111(a)(1) is revised to read as follows:

§ 146.111 Preexisting condition exclusions.

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

* * * * *

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

■ 32. The authority citation for part 147 continues to read as follows:

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

■ 33. Section 147.108 is revised to read as follows:

§ 147.108 Prohibition of preexisting condition exclusions.

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

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

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N’s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

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

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

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

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

(A) The practice is permitted under State law;

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

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

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

(2) *Restrictions.* A health insurance issuer offering individual health insurance coverage may screen applicants for eligibility for alternative coverage provided that:

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

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

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

(d) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation,

plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

■ 34. Section 147.120 is revised to read as follows:

§ 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.

■ 35. Section 147.126 is revised to read as follows:

§ 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 this purpose, 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 consistent with one of the three Federal Employees Health Benefit Program (FEHBP) options as defined by 45 CFR 156.100(a)(3) or one of the base-benchmark plans selected by a State or applied by default pursuant to 45 CFR 156.100.

(d) *Special rule for health reimbursement arrangements (HRAs) and other account-based plans*—(1) *In general.* If an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based plan are limited does not mean that the HRA or other account-based plan fails to meet the requirements of paragraph (a)(2) of this section. Similarly, if an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in PHS Act section 2713 and § 147.130(a)(1), the HRA or other account-based plan will not fail to meet the requirements of PHS Act 2713 and § 147.130(a)(1).

(2) *Integration requirements.* An HRA or other account-based plan is integrated with a group health plan for purposes of paragraph (a)(2) of this section if it meets the requirements under either the integration method set forth in paragraph (d)(2)(i) of this section or the integration method set forth in paragraph (d)(2)(ii) of this section. Integration does not require that the HRA (or other account-based plan) and the 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. The term “excepted benefits” is used throughout the integration methods; for a definition of the term “excepted benefits” see Internal Revenue Code section 9832(c), ERISA section 733(c), and PHS Act section 2791(c).

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

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

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan (other than the HRA or other account-based 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 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 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 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 (as defined under section 213(d) of the Internal Revenue Code) that does 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 plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(ii) *Integration Method: Minimum value required.* An HRA or other account-based plan is integrated with

another group health plan for purposes of this paragraph if:

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

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Internal Revenue Code (and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based 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 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 plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(3) *Forfeiture.* For purpose 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 this purpose coverage under an HRA or other account-based 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 plan. This means that upon and after reinstatement, the reinstated amounts under the HRA or

other account-based plan may not be used to reimburse or pay medical expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *No integration with individual market coverage.* A group health plan, including an HRA or other account-based plan, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of paragraph (a)(2) of this section (or for purposes of the requirements of PHS Act section 2713).

(5) *Integration with Medicare parts 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 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 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 plan is actually enrolled Medicare part B or D;

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

(iv) The HRA or other account-based plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Account-based plan.* An account-based plan for purposes of this section is an employer-provided group health plan that provides reimbursements of medical expenses other than individual market policy premiums with the reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based plan.

(e) *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.

■ 36. Section 147.128 is revised to read as follows:

§ 147.128 Rules regarding rescissions.

(a) *Prohibition on rescissions.*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

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

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

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

(iii) The cancellation or discontinuance of coverage is initiated by the individual (or by the individual's

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

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

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

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146 of this subchapter. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A*'s visits to the psychologist, which was not disclosed in the questionnaire.

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

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

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

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

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

■ 37. Section 147.136 is revised to read as follows:

§ 147.136 Internal claims and appeals and external review processes.

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

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage, as described in § 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant.* *Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review.* *External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process—(1) In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must

comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an “adverse benefit determination” includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan’s benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(1) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or

issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan’s benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(1) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must provide to participants, beneficiaries and enrollees, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(3) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan’s or issuer’s standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(4) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(5) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes—(1)* In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(2) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as

applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(2) Notwithstanding paragraph (b)(2)(ii)(F)(1) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(1) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(2), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503-1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(3) *Requirements for individual health insurance issuers.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of this paragraph (b)(3).

(i) *Minimum internal claims and appeals standards.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of the ERISA internal claims and appeals procedures applicable to group health plans under 29 CFR 2560.503-1 except for the requirements with respect to multiemployer plans, and except to the extent those requirements are modified by paragraph (b)(3)(ii) of this section. Accordingly, under this paragraph (b), with respect to individual health insurance coverage, the issuer is subject to the requirements in 29 CFR 2560.503-1 as if the issuer were a group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(3)(i) of this section, the internal claims and appeals processes of a health insurance issuer offering individual health insurance coverage must meet the requirements of this paragraph (b)(3)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(3), an adverse benefit determination includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503-1, as well as other provisions of this paragraph (b)(3), an issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) and any decision to deny coverage in an initial eligibility determination as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503-1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the issuer's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503-1(m)(1), as determined by the attending provider, and the issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* An issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503-1(h)(2)—

(1) The issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the issuer (or at the direction of the issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503-1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503-1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503-1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the issuer shall notify the claimant of the issuer's determination as soon as an issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) Avoiding conflicts of interest. In addition to the requirements of 29 CFR 2560.503-1(b) and (h) regarding full and fair review, the issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* An issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The issuer must also comply with the additional requirements of this paragraph (b)(3)(ii)(E).

(1) The issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the name of the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(3) The issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(4) The issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(5) The issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (1) In the case of an issuer that fails to adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided

in paragraph (b)(3)(ii)(F)(2) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under State law, as applicable, on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(2) Notwithstanding paragraph (b)(3)(ii)(F)(1) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the issuer demonstrates that the violation was for good cause or due to matters beyond the control of the issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the issuer and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the issuer. The claimant may request a written explanation of the violation from the issuer, and the issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(3)(ii)(F)(1) of this section on the basis that the issuer met the standards for the exception under this paragraph (b)(3)(ii)(F)(2), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the issuer shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(G) *One level of internal appeal.* Notwithstanding the requirements in 29 CFR 2560.503–1(c)(3), a health insurance issuer offering individual health insurance coverage must provide for only one level of internal appeal before issuing a final determination.

(H) *Recordkeeping requirements.* A health insurance issuer offering individual health insurance coverage must maintain for six years records of all claims and notices associated with the internal claims and appeals process, including the information detailed in

paragraph (b)(3)(ii)(E) of this section and any other information specified by the Secretary. An issuer must make such records available for examination by the claimant or State or Federal oversight agency upon request.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* An issuer subject to the requirements of this paragraph (b)(3) is required to provide continued coverage pending the outcome of an appeal. For this purpose, the issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii) as if the issuer were a group health plan, so that the issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.

(c) *State standards for external review—(1) In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group or individual health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then

the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section); or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed \$25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year must not exceed \$75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a \$500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The

process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans)

include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process*. A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external

review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope*—(i) *In general*. The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812, 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 or beneficiary 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)); and

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

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

Example 1. (i) Facts. A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual A seeks coverage for a 31st physical therapy visit. A's health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, A receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion*. In this *Example 1*, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term.

Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) Facts. A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual B seeks coverage for a specialized medical procedure from an out-of-network provider because B believes that the procedure cannot be effectively provided in network. B receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion*. In this *Example 2*, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network.

Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(2) *External review process standards*. The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model

Act and, therefore satisfies the requirements of paragraph (d)(2) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

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

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

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

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

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

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must

describe the information or materials needed to make the request complete and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization.* (A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

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

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

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

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

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

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

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

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

terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(4) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(5) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(i) The claimant's medical records;

(ii) The attending health care professional's recommendation;

(iii) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(iv) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(v) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(vi) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(vii) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(6) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(7) The assigned IRO's written notice of the final external review decision must contain the following:

(i) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(ii) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(iii) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(iv) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(v) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(vi) A statement that judicial review may be available to the claimant; and

(vii) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(viii) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(iv) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section and a self-insured nonfederal governmental plan may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the Federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice—(1) In general.* For purposes of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the

applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements*—(i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

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

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

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

(g) *Applicability date*. The provisions of this section 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.

■ 38. Section 147.138 is revised to read as follows:

§ 147.138 Patient protections.

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

designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction*. Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example*. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts*. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion*. In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general*. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction*. Nothing in paragraph (a)(2)(i) of this section is to be

construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

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

Example 1. (i) *Facts*. A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(ii) *Conclusion*. In this *Example 1*, the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts*. Same facts as *Example 1*, except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion*. In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access*. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a

health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

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

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that A seeks gynecological services from C, an out-of-network provider.

(ii) *Conclusion.* In this *Example 2*, the group health plan has not violated the

requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider—*(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph

(a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services—*(1) *Scope.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for

emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount at least equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (B), and (C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under

this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket

maximum must apply to out-of-network emergency services.

(iii) *Special rules regarding out-of-network minimum payment standards*—

(A) The minimum payment standards set forth under paragraph (b)(3) of this section do not apply in cases where State law prohibits a participant, beneficiary, or enrollee from being required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer provides in benefits, or where a group health plan or health insurance issuer is contractually responsible for such amounts. Nonetheless, in such cases, a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in network.

(B) A group health plan and health insurance issuer must provide a participant, beneficiary, or enrollee adequate and prominent notice of their lack of financial responsibility with respect to the amounts described under this paragraph (b)(3)(iii), to prevent inadvertent payment by the participant, beneficiary, or enrollee.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) Facts. A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1*, the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a \$60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2*, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates

the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept \$85, two have agreed to accept \$100, two have agreed to accept \$110, three have agreed to accept \$120, and one has agreed to accept \$150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3*, the values taken into account in determining the median are \$85, \$100, \$100, \$110, \$110, \$120, \$120, \$120, and \$150. Therefore, the median amount among those agreed to for the emergency service is \$110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of \$110 (\$88).

Example 4. (i) *Facts.* Same facts as *Example 3*. Subsequently, the plan adds another provider to its network, who has agreed to accept \$150 for the emergency service.

(ii) *Conclusion.* In this *Example 4*, the median amount among those agreed to for the emergency service is \$115. (Because there is no one middle amount, the median is the average of the two middle amounts, \$110 and \$120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of \$115 (\$92).

Example 5. (i) *Facts.* Same facts as *Example 4*. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges \$125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is \$116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is \$80.

(ii) *Conclusion.* In this *Example 5*, the plan is responsible for paying \$92.80, 80% of \$116. The median amount among those agreed to for the emergency service is \$115 and the amount the plan would pay is \$92 (80% of \$115); the amount calculated using the same method the plan uses to determine

payments for out-of-network services—\$116—excluding the in-network 20% coinsurance, is \$92.80; and the Medicare payment is \$80. Thus, the greatest amount is \$92.80. The individual is responsible for the remaining \$32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5*. The group health plan generally imposes a \$250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a \$500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted \$260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6*, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

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

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

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the

Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

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

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning 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.

■ 39. Section 147.140 is revised to read as follows:

§ 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage—(1) In general—(i) Grandfathered health plan coverage* means coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage. Accordingly, if any benefit package relinquishes grandfather status, it will not affect the

grandfather status of the other benefit packages.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

(2) *Disclosure of grandfather status—*
(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act, and must provide contact information for questions and complaints, in any summary of benefits provided under the plan.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a “grandfathered health plan” under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime dollar limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1-866-444-3272 or www.dol.gov/ebsa/healthreform. This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at www.healthcare.gov.]

(3)(i) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(A) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(B) Make such records available for examination upon request.

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual dollar limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) *Allowance for new employees to join current plan—*(1) *In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010. Further, the addition of a new contributing employer or new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan’s grandfather status.

(2) *Anti-abuse rules—*(i) *Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(iii) *Illustrative list of bona fide employment-based reasons.* For purposes of this paragraph (b)(2)(ii)(C), bona fide employment-based reasons include—

(A) When a benefit package is being eliminated because the issuer is exiting the market;

(B) When a benefit package is being eliminated because the issuer no longer offers the product to the employer;

(C) When low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package;

(D) When a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or

(E) When a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.

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

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *F* and *G*. During a subsequent open enrollment period, some of the employees enrolled in Option *F* on March 23, 2010 switch to Option *G*.

(ii) *Conclusion.* In this *Example 1*, the group health coverage provided under Option *G* remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option *F* are allowed to enroll in Option *G* as new employees.

Example 2. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *H* and *I*. On March 23, 2010, Option *H* provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates

Option *H* and the employees that are moved are transferred to Option *I*. If instead of transferring employees from Option *H* to Option *I*, Option *H* was amended to match the terms of Option *I*, then Option *H* would cease to be a grandfathered health plan.

(ii) *Conclusion*. In this *Example 2*, the plan has a bona fide employment-based reason to transfer employees from Option *H* to Option *I*. Therefore, Option *I* does not cease to be a grandfathered health plan.

(c) *General grandfathering rule*—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual dollar limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans*. The provisions of PHS Act section 2711 insofar as it relates to lifetime dollar limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it

relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans*—*In general*. In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with

the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status*. Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. 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)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment*. Any increase in a fixed-amount copayment, determined as of the effective date of the increase, 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)(3)(i) of this section (that is, \$5 times medical inflation, plus \$5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(C) *Special rules regarding decreases in contribution rates.* An insured group health plan (or a multiemployer plan) that is a grandfathered health plan will not cease to be a grandfathered health plan based on a change in the employer contribution rate unless the issuer (or multiemployer plan) knows, or should know, of the change, provided:

(1) Upon renewal (or, in the case of a multiemployer plan, before the start of a new plan year), the issuer (or multiemployer plan) requires relevant employers, employee organizations, or plan sponsors, as applicable, to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer, or

multiemployer plan, does not already have it); and

(2) The relevant policies, certificates, contracts of insurance, or plan documents disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year.

(D) *Application to plans with multi-tiered coverage structures.* The standards for employer contributions in this paragraph (g)(1)(v) apply on a tier-by-tier basis. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.*, self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.*, at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage would not cause the plan to lose grandfather status.

(E) *Group health plans with fixed-dollar employee contributions or no employee contributions.* A group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan solely because the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage.

(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) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI-U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI-U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

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

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment requirement of \$30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to \$40. Within the 12-month period before the \$40 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3*, the increase in the copayment from \$30 to \$40, expressed as a percentage, is 33.33% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). The maximum percentage increase permitted is 37.69% ($0.2269 = 22.69\%$; $22.69\% + 15\% = 37.69\%$). Because 33.33% does not exceed 37.69%, the change

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

Example 4. (i) *Facts.* Same facts as *Example 3*, except the grandfathered health plan subsequently increases the \$40 copayment requirement to \$45 for a later plan year. Within the 12-month period before the \$45 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4*, the increase in the copayment from \$30 (the copayment that was in effect on March 23, 2010) to \$45, expressed as a percentage, is 50% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% ($0.2527 = 25.27\%$; $25.27\% + 15\% = 40.27\%$), or \$6.26 ($\$5 \times 0.2527 = \1.26 ; $\$1.26 + \$5 = \$6.26$). Because 50% exceeds 40.27% and \$15 exceeds \$6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment of \$10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$15. Within the 12-month period before the \$15 copayment takes effect, the greatest value of the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(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) of this section is the greater of the maximum percentage increase of 22.20% ($0.0720 = 7.20\%$; $7.20\% + 15\% = 22.20\%$), or \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to \$5.36.

Example 6. (i) *Facts.* The same facts as *Example 5*, except on March 23, 2010, the grandfathered health plan has no copayment (\$0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to \$5.

(ii) *Conclusion.* In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 ($415.0 - 387.142 = 27.858$; $27.858 \div 387.142 = 0.0720$). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is \$5.36 ($\$5 \times 0.0720 = \0.36 ; $\$0.36 + \$5 = \$5.36$). The \$5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of \$5.36. Thus, the \$5 increase

in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) Facts. On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) Conclusion. In this *Example 7*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) Facts. On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of \$5000 for self-only coverage and \$12,000 for family coverage. The required employee

contribution for the coverage is \$1000 for self-only coverage and \$4000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% $((5000 - 1000)/5000)$ for self-only coverage and 67% $((12,000 - 4000)/12,000)$ for family coverage. For a subsequent plan year, the COBRA premium is \$6000 for self-only coverage and \$15,000 for family coverage. The employee contributions for that plan year are \$1200 for self-only coverage and \$5000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% $((6000 - 1200)/6000)$ for self-only coverage and 67% $((15,000 - 5000)/15,000)$ for family coverage.

(ii) Conclusion. In this *Example 8*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax

through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) Facts. A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) Conclusion. In this *Example 9*, the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the (rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

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