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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB43

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OCIIO-9994-IFC

45 CFR Parts 144, 146, and 147

RIN 0991-AB69

Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under

provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, and patient protections.

DATES: Effective date. These interim final regulations are effective on [**INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER**].

Comment date. Comments are due on or before [**INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER**].

Applicability dates:

1. Group health plans and group health insurance coverage. These interim final regulations, except those under Public Health Service Act (PHS Act) section 2704 (26 CFR 54.9815-2704T, 29 CFR 2590.715-2704, 45 CFR 147.108), generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations under PHS Act section 2704 (26 CFR 54.9815-2704T, 29 CFR 2590.715-2704, 45 CFR 147.108) generally apply for plan years beginning on or after January 1, 2014, except that in the case of individuals who are under 19 years of age, these interim final regulations under PHS Act section 2704 apply for plan years beginning on or after September 23, 2010.

2. Individual health insurance coverage. These interim final regulations, except those under PHS Act section 2704 (45 CFR 147.108), generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010. These interim final regulations under PHS Act section 2704 (45 CFR 147.108) generally apply to individual health insurance issuers for policy years beginning on or after January 1, 2014, except that in the case of enrollees who are under 19 years of age, these interim final regulations under PHS Act section 2704 apply for policy years beginning on or after September 23, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **WARNING**: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB43, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Email: E-OHPSCA715.EBSA@dol.gov.
- Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: RIN 1210-AB43.

Comments received by the Department of Labor will be posted without change to http://www.regulations.gov and http://www.dol.gov/ebsa, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIIO-9994-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions under the "More Search Options" tab.
- By regular mail. You may mail written comments to the following address ONLY:

  Office of Consumer Information and Insurance Oversight

  Department of Health and Human Services,

  Attention: OCIIO-9994-IFC,

  P.O. Box 8016,

  Baltimore, MD 21244-1850.

  Please allow sufficient time for mailed comments to be received before the close of the comment period.

- By express or overnight mail. You may send written comments to the following address ONLY:

  Office of Consumer Information and Insurance Oversight,

  Department of Health and Human Services,

  Attention: OCIIO-9994-IFC,

  Mail Stop C4-26-05,

  7500 Security Boulevard,

  Baltimore, MD 21244-1850.

- By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:
    - For delivery in Washington, DC--

Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

- For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, please call (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1-800-743-3951.

Internal Revenue Service. Comments to the IRS, identified by REG-120399-10, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

- Mail: CC:PA:LPD:PR (REG-120399-10), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

- Hand or courier delivery: Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-120399-10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in Room 1621, 1111 Constitution Avenue, NW, Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786-1565. *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 website (http://www.dol.gov/ebsa). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at http://www.healthreform.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Pub. L. 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Pub. L. 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add 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 by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724[2] (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended 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 group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers requirements that are stricter than the requirements imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

[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.

[2] Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations in several phases implementing the revised PHS Act sections 2701 through 2719A and related provisions of the Affordable Care Act. The first phase in this series was a pair of publications consisting of a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718 and a Request for Information relating to the rate review process of PHS Act 2794, both published in the **Federal Register** on April 14, 2010 (75 FR 19297 and 19335). The second phase was interim final regulations implementing PHS Act section 2714 (requiring coverage of adult children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third phase was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on June 17, 2010 (75 FR 34538). These interim final regulations are being published to implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections). PHS Act section 2704 generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, PHS Act section 2704 is effective for plan years beginning on or after September 23, 2010 (which is six months after the March 23, 2010 date of enactment of the Affordable Care Act); or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.[3] The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

[3] Section 1255 of the Affordable Care Act. See also section 10103(e)-(f) of the Affordable Care Act.

II. Overview of the Regulations

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

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA[4] 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 may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusion from being imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010. Until the new Affordable Care Act rules take effect, the HIPAA rules regarding preexisting condition exclusions continue to apply.

HIPAA generally defines a preexisting condition exclusion[5] 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, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific

[4] HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).
[5] Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). See also ERISA section 701(b)(1) and Code section 9801(b)(1).

benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

The protections in the new PHS Act section 2704 generally apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In order for an individual seeking enrollment to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied enrollment or specific benefits based on a preexisting condition. Thus, for plan years (in the individual market, policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan or health insurance coverage (through denial of enrollment or denial of specific benefits) based on the preexisting condition.

These interim final regulations do not change the HIPAA rule that an exclusion of benefits for a condition under a plan or policy is not a preexisting condition exclusion if the exclusion applies regardless of when the condition arose relative to the effective date of coverage. This point is illustrated with examples in the HIPAA regulations on preexisting condition exclusions, which remain in effect.[6] (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

Application to grandfathered health plans. Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the PHS Act section 2704 prohibition against preexisting condition

[6] See Examples 6, 7, and 8 in 26 CFR 54.9801-3(a)(1)(ii), 29 CFR 701-3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 regarding status as a grandfathered health plan.

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

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits.

The restriction on annual limits applies differently to certain account-based plans, especially where other rules apply to limit the benefits available. For example, under section 9005 of the Affordable Care Act, salary reduction contributions for health flexible spending arrangements (health FSAs) are specifically limited to $2,500 (indexed for inflation) per year, beginning with taxable years in 2013. These interim final regulations provide that the PHS Act section 2711 annual limit rules do not apply to health FSAs. The restrictions on annual limits also do not apply to Medical Savings Accounts (MSAs) under section 220 of the Code and Health Savings Accounts (HSAs) under section 223 of the Code. Both MSAs and HSAs generally are not treated as group health plans because the amounts available under the plans are available for both medical and non-medical expenses.[7] Moreover, annual contributions to MSAs and HSAs are subject to specific statutory provisions that require that the contributions be limited.

Health Reimbursement Arrangements (HRAs) are another type of account-based health plan and typically consist of a promise by an employer to reimburse medical expenses for the

[7] Distributions from MSAs and HSAs that are not used for qualified medical expenses are included in income and subject to an additional tax, under sections 220(f)(1), (4) and 223(f)(1), (4) of the Code.

year up to a certain amount, with unused amounts available to reimburse medical expenses in future years. See Notice 2002-45, 2002-28 IRB 93; Rev. Rul. 2002-41, 2002-28 IRB 75. When HRAs are integrated with other coverage as part of a group health plan and the other coverage alone would comply with the requirements of PHS Act section 2711, the fact that benefits under the HRA by itself are limited does not violate PHS Act section 2711 because the combined benefit satisfies the requirements. Also, in the case of a stand-alone HRA that is limited to retirees, the exemption from the requirements of ERISA and the Code relating to the Affordable Care Act for plans with fewer than two current employees means that the retiree-only HRA is generally not subject to the rules in PHS Act section 2711 relating to annual limits. The Departments request comments regarding the application of PHS Act section 2711 to stand-alone HRAs that are not retiree-only plans.

The statute prohibits annual limits on the dollar value of benefits generally, but allows "restricted annual limits" with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. Grandfathered individual market policies are exempted from this provision. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per-individual dollar limits on specific covered benefits. These interim final regulations define "essential health benefits" by cross-reference to section 1302(b) of the Affordable Care Act[8] and applicable regulations. Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

[8] Section 1302(b) of the Affordable Care Act defines essential health benefits to "include at least the following general categories and the items and services covered within the categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care."

For 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". For this purpose, a plan or issuer must apply the definition of essential health benefits consistently. For example, a plan could not both apply a lifetime limit to a particular benefit – thus taking the position that it was not an essential health benefit – and at the same time treat that particular benefit as an essential health benefit for purposes of applying the restricted annual limit.

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that in defining the term restricted annual limit, the Departments should ensure that access to needed services is made available with a minimal impact on premiums. For a detailed discussion of the basis for determining restricted annual limits, see section IV.B.3 later in this preamble.

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. Under these interim final regulations, annual limits on the dollar value of benefits that are essential health benefits may not be less than

the following amounts for plan years (in the individual market, policy years) beginning before January 1, 2014:

- 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.

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the $2 million minimum annual limit is available; however, a plan or policy generally may not impose an annual limit for a plan year (in the individual market, policy year) beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan or health insurance coverage may take into account only essential health benefits.

The restricted annual limits provided in these interim final regulations are designed to ensure, in the vast majority of cases, that individuals would have access to needed services with a

minimal impact on premiums. So that individuals with certain coverage, including coverage under a limited benefit plan or so-called "mini-med" plans, would not be denied access to needed services or experience more than a minimal impact on premiums, these interim final regulations provide for the Secretary of Health and Human Services to establish a program under which the requirements relating to restricted annual limits may be waived if compliance with these interim final regulations would result in a significant decrease in access to benefits or a significant increase in premiums. Guidance from the Secretary of Health and Human Services regarding the scope and process for applying for a waiver is expected to be issued in the near future.

Under these interim final regulations, individuals who reached a lifetime limit under a plan or health insurance coverage prior to the applicability date of these interim final regulations and are otherwise still eligible under the plan or health insurance coverage must be provided with a notice that the lifetime limit no longer applies. If such individuals are no longer enrolled in the plan or health insurance coverage, these interim final regulations also provide an enrollment (in the individual market, reinstatement) opportunity for such individuals. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits on individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. These notices and the enrollment opportunity must be provided beginning not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. Anyone eligible for an enrollment opportunity must be treated as a special enrollee.[9] That is, they must be given the right to enroll in all of the benefit packages available to similarly situated individuals upon initial enrollment.

[9] See 26 CFR 54.9801-6(d), 29 CFR 2590.701-6(d), and 45 CFR 146.117(d).

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage, whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage. The interim final regulations issued under section 1251 of the Affordable Care Act provide that:

- 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.
- 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.
- 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).

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

PHS Act section 2712 provides rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard sets a Federal floor and is more protective of individuals with respect to the standard for rescission than the standard that might have previously existed under State insurance law or Federal common law. That is, under prior law, rescission may have been permissible if an individual made a misrepresentation of material fact, even if the misrepresentation was not intentional or made knowingly. Under the new standard for rescissions set forth in PHS Act section 2712 and these interim final regulations, plans and issuers cannot rescind coverage unless an individual was involved in fraud or made an intentional misrepresentation of material fact. This standard applies to all rescissions, whether in the group or individual insurance market, and whether insured or self-insured coverage. These rules also apply regardless of any contestability period that may otherwise apply.

This provision in PHS Act section 2712 builds on already-existing protections in PHS Act sections 2703(b) and 2742(b) regarding cancellations of coverage. These provisions generally provide that a health insurance issuer in the group and individual markets cannot cancel, or fail to renew, coverage for an individual or a group for any reason other than those enumerated in the statute (that is, nonpayment of premiums; fraud or intentional

misrepresentation of material fact; withdrawal of a product or withdrawal of an issuer from the market; movement of an individual or an employer outside the service area; or, for bona fide association coverage, cessation of association membership). Moreover, this new provision also builds on existing HIPAA nondiscrimination protections for group health coverage in ERISA section 702, Code section 9802, and PHS Act section 2705 (previously included in PHS Act section 2702 prior to the Affordable Care Act's amendments and reorganization to PHS Act title XXVII). The HIPAA nondiscrimination provisions generally provide that group health plans and group health insurance issuers may not set eligibility rules based on factors such as health status and evidence of insurability – including acts of domestic violence or disability. They also provide limits on the ability of plans and issuers to vary premiums and contributions based on health status. For policy years beginning on or after January 1, 2014, additional protections will apply in the individual market, including guaranteed issue of all products, nondiscrimination based on health status, and no preexisting condition exclusions. These protections will reduce the likelihood of rescissions.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission or cancellation of coverage beyond the standards established in PHS Act section 2712, if they are more protective of individuals. For example, if a State law applicable to health insurance issuers were to provide that rescissions are permitted only in cases of fraud, or only within a contestability period, which is more protective of individuals, such a law would not conflict with, or be preempted by, the Federal standard and would apply.

These interim final regulations include several clarifications regarding the standards for rescission in PHS Act section 2712. First, these interim final regulations clarify that the rules of

PHS Act section 2712 apply whether the rescission applies to a single individual, an individual within a family, or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employment-based group because of the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

For purposes of these interim final regulations, 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 with only a prospective effect is not a rescission, and neither is a cancellation or discontinuance of coverage that is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage. Cancellations of coverage are addressed under other Federal and State laws, including section PHS Act section 2703(b) and 2742(b), which limit the grounds for cancellation or non-renewal of coverage, as discussed above. Moreover,

PHS Act section 2719, as added by the Affordable Care Act and incorporated in ERISA section 715 and Code section 9815, addresses appeals of coverage determinations and includes provisions for keeping coverage in effect pending an appeal. The Departments expect to issue guidance on PHS Act section 2719 in the very near future.

In addition to setting a new Federal floor standard for rescissions, PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided. These interim 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.[10] The notice must be provided regardless of whether the rescission is 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. This 30-day period will provide individuals and plan sponsors with an opportunity to explore their rights to contest the rescission, or look for alternative coverage, as appropriate. The Departments expect to issue future guidance on any notice requirements under PHS Act section 2712 for cancellations of coverage other than in the case of rescission.

In this new Federal statutory protection against rescissions, the Affordable Care Act provides new rights to individuals who, for example, may have done their best to complete what can sometimes be long, complex enrollment questionnaires but may have made some errors, for which the consequences were overly broad and unfair. These interim final regulations provide initial guidance with respect to the statutory restrictions on rescission. If the Departments

[10] Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

become aware of attempts in the marketplace to subvert these rules, the Departments may issue additional regulations or administrative guidance to ensure that individuals do not lose health coverage unjustly or without due process.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815-2719AT, 29 CFR 2590.715-2719A, 45 CFR 147.138)

Section 2719A of the PHS Act 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 a health care professional and requirements relating to benefits for emergency services. The three requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers.[11] Thus, a plan or issuer that has not negotiated with any provider for the delivery of health care but merely reimburses individuals covered under the plan for their receipt of health care is not subject to the requirements relating to the choice of a health care professional. However, such plans or health insurance coverage are subject to requirements relating to benefits for emergency services. These interim final regulations reorder the statutory requirements so that all three of the requirements relating to the choice of a health care professional are together and add a notice requirement for those three requirements. None of these requirements apply to grandfathered health plans.

1. Choice of Health Care Professional

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

[11] The statute and these interim final regulations refer to providers both in terms of their participation (participating provider) and in terms of a network (in-network provider). In both situations, the intent is to refer to a provider that has a contractual relationship or other arrangement with a plan or issuer.

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. Under these interim final regulations, the plan or issuer must provide a notice informing each participant (or in the individual market, the primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

The statute and these interim final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, 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. In such a case, the plan or issuer must comply with the notice requirements with respect to designation of a primary care provider. 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.

The statute and these interim 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. In such a case, 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. The plan or issuer must

inform each participant (in the individual market, primary subscriber) that the plan or issuer may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. Nothing in these interim final regulations precludes the plan or issuer from requiring an in-network obstetrical or gynecological provider to otherwise adhere to policies and procedures regarding referrals, prior authorization for treatments, and the provision of services pursuant to a treatment plan approved by the plan or issuer. The plan or issuer must 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 who specializes 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.

The general terms of the plan or coverage regarding exclusions of coverage with respect to obstetrical or gynecological care are otherwise unaffected. These interim final regulations do not preclude the plan or issuer from requiring that the obstetrical or gynecological provider notify the primary care provider or the plan or issuer of treatment decisions.

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 designation of a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, these interim 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 interim 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.

2. Emergency Services

If a plan or health insurance coverage provides any benefits with respect to emergency services in an emergency department of a hospital, the plan or issuer must cover emergency services in a way that is consistent with these interim final regulations. These interim final regulations require that a plan or health insurance coverage providing 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) and without regard to whether the health care provider furnishing the emergency services is an in-network provider with respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or health insurance coverage other than the exclusion or coordination of benefits, 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 Code, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides 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.

Additionally, for a plan or health insurance coverage with a network, these interim final regulations provide rules for cost-sharing requirements for emergency services that are expressed as a copayment amount or coinsurance rate, and other 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. Out-of-network providers may, however, also balance bill patients for the difference between the providers' charges and the amount collected from the plan or issuer and from the patient in the form of a copayment or coinsurance amount. 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 cost sharing expressed as a copayment or coinsurance rate.

Because the statute does not require plans or issuers to cover balance billing amounts, and does not prohibit balance billing, even where the protections in the statute apply, patients may be subject to balance billing. 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. To avoid the circumvention of the protections of PHS Act section 2719A, it is necessary that a reasonable amount be paid before a patient becomes responsible for a balance billing amount. Thus, these interim final regulations require that a reasonable amount be paid for services by some objective standard. In establishing the reasonable amount that must be paid, the Departments had to account for wide variation in how plans and issuers determine both in-network and out-of-network rates. For example, for a plan using a capitation arrangement to determine in-network payments to providers, there is no in-network rate per service. Accordingly, these interim final regulations consider three amounts: the in-network rate, the out-of-network rate, and the Medicare rate. Specifically, a plan or issuer satisfies the copayment and coinsurance limitations

in the statute if it provides benefits for out-of-network emergency services in an amount equal to the greatest of three possible amounts—

(1) The amount negotiated with in-network providers for the emergency service furnished;

(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 charges) but substituting the in-network cost-sharing provisions for the out-of-network cost-sharing provisions; or

(3) The amount that would be paid under Medicare for the emergency service.[12]

Each of these three amounts is calculated excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

For plans and health insurance coverage under which there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the first amount above is disregarded, meaning that the greatest amount is going to be either the out-of-network amount or the Medicare amount. Additionally, with respect to determining the first amount, if a plan or issuer has more than one negotiated amount with in-network providers for a particular emergency service, the amount is the median of these amounts, treating the amount negotiated with each provider as a separate amount in determining the median. Thus, for example, if for a given emergency service a plan negotiated a rate of $100 with three providers, a rate of $125 with one provider, and a rate of $150 with one provider; the amounts taken into account to determine the median would be $100, $100, $100, $125, and $150; and the median would be $100. Following the commonly accepted definition of median, if

[12] As of the date of publication of these interim final regulations, these rates are available to the public at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf.

there are an even number of amounts, the median is the average of the middle two. (Cost sharing imposed with respect to the participant, beneficiary, or enrollee would be deducted from this amount before determining the greatest of the three amounts above.)

The second amount above 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 second amount above 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).

Although a plan or health insurance coverage is generally not constrained by the requirements of PHS Act section 2719A for cost-sharing requirements other than copayments or coinsurance, these interim final regulations include an anti-abuse rule with respect to such other cost-sharing requirements so that the purpose of limiting copayments and coinsurance for emergency services to the in-network rate cannot be thwarted by manipulation of these other cost-sharing requirements. Accordingly, any other cost-sharing requirement, such as a deductible or out-of-pocket maximum, may be imposed with respect to out-of-network emergency services only if the cost-sharing requirement generally applies to out-of-network benefits. Specifically, 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. Similarly, 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. A plan or health insurance

coverage could fashion these other cost-sharing requirements so that a participant, beneficiary, or enrollee is required to pay less for emergency services than for general out-of-network services; the anti-abuse rule merely prohibits a plan or health insurance coverage from fashioning such rules so that a participant, beneficiary, or enrollee is required to pay more for emergency services than for general out-of-network services.

In applying the rules relating to emergency services, the statute and these interim final regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under the Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act. There are, however, some minor variances from the EMTALA definitions. For example, both EMTALA and PHS Act section 2719A define "emergency medical condition" in terms of the same consequences that could reasonably be expected to occur in the absence of immediate medical attention. Under EMTALA regulations, the likelihood of these consequences is determined by qualified hospital medical personnel, while under PHS Act section 2719A the standard is whether a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in such consequences.

Application to grandfathered health plans. The statute and these interim final regulations 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.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Moreover, the requirements in these interim final regulations require significant lead time in order to implement. For example, in the case of the requirement under PHS Act section 2711 prohibiting

overall lifetime dollar limits, these interim final regulations require that an enrollment opportunity be provided for an individual whose coverage ended by reason of reaching a lifetime limit no later than the first day this requirement takes effect. Preparations presumably would have to be made to put such an enrollment process in place. In the case of requirements for emergency care under PHS Act section 2719A, plans and issuers need to know how to process charges by out-of-network providers by as early as the first plan or policy year beginning on or after September 23, 2010. With respect to all the changes that would be required to be made under these interim final regulations, whether adding coverage of children with a preexisting condition under PHS Act section 2704, or determining the scope of rescissions prohibited under PHS Act section 2712, group health plans and health insurance issuers have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

Accordingly, in order to allow plans and health insurance coverage to be designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the

necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

A. Summary--Department of Labor and Department of Health and Human Services

As stated earlier in this preamble, these interim final regulations implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (prohibiting lifetime and annual dollar limits on benefits), 2712 (rules regarding rescissions), and 2719A (patient protections). [13] These interim final regulations also provide guidance on the requirement to provide enrollment opportunities to individuals who reached a lifetime limit. PHS Act section 2704 regarding preexisting condition exclusions generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, this section is effective for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning on or after September 23, 2010.[14] The rest of these provisions generally are effective for plan years (in the individual market, policy

[13] The Affordable Care Act adds Section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, under ERISA and the Code as if those provisions of the PHS Act were included in ERISA and the Code.

[14] Section 1255 of the Affordable Care Act. See also section 10103(e)-(f) of the Affordable Care Act.

years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act.

The Departments have crafted these interim final regulations to secure the protections intended by Congress in the most economically efficient manner possible. In accordance with OMB Circular A-4, they have quantified the benefits and costs where possible and provided a qualitative discussion of some of the benefits and the costs that may stem from these interim final regulations.

B. Executive Order 12866--Department of Labor and Department of Health and Human Services

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. OMB has determined that this rule is significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an effect on the economy of $100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order. The Departments provide an assessment of the

potential costs and benefits of each regulatory provision below, summarized in the following table.

Table 1.1 Accounting Table

TABLE 1.1--*Accounting Table*

Benefits

Qualitative: These patient protections are expected to expand coverage for children with preexisting conditions and individuals who face rescissions, lifetime limits, and annual limits as a result of high health care costs. Expanded coverage is likely to increase access to health care, improve health outcomes, improve worker productivity, and reduce family financial strain and "job lock". Many of these benefits have a distributional component, and promote equity, in the sense that they will be enjoyed by those who are especially vulnerable as a result of health problems and financial status. Choice of physician will likely lead to better, sustained patient-provider relationships, resulting in decreased malpractice claims and improved medication adherence and health promotion. Removing referrals and prior authorizations for primary care, obstetrical and gynecological care, and emergency services is likely to reduce administrative and time burdens on both patients and physicians, while improving health outcomes by allowing quicker access to medical services when necessary.

Costs	**Estimate**	**Year Dollar**	**Discount Rate**	**Period Covered**[15]
Annualized Monetized ($millions/year)	4.9	2010	7%	2011-2013
	4.9	2010	3%	2011-2013

Monetized costs are due to a requirement to notify participants that exceeded their lifetime limit and were disenrolled from their plan or coverage of their right to re-enroll in the plan; a requirement that a group health plan or a health insurance issuer offering group or individual health insurance coverage must notify an affected individual 30 days before coverage may be rescinded; and a notice of a participant's right to choose any available participating primary care provider or pediatrician as their primary care provider, and of increased protections for those participants seeking emergency services.

Qualitative: To the extent these patient protections increase access to health care services, increased health care utilization and costs will result due to increased uptake. Expanding coverage to children with preexisting conditions and individuals subject to rescissions will likely increase overall health care costs, given that these groups tend to have high cost conditions and require more costly care than average.

Transfers

Qualitative: These patient protections create a small transfer from those paying premiums in the group market to those obtaining the increased patient protections. To the extent there is risk pooling in the individual market, a similar transfer will occur.

1. Need for Regulatory Action

a. Preexisting condition exclusions

As discussed earlier in this preamble, Section 2704 of the PHS Act as added by the Affordable Care Act, prohibits group health plans and health insurance issuers offering group or

[15] The Departments' analysis extends to 2013. The analysis does not attempt to estimate effects in 2014 and beyond because the extensive changes provided for by the Affordable Care Act in sources of coverage, rating rules, and the structure of insurance markets make it nearly impossible to isolate the effects of the provisions of these interim final regulations.

individual health insurance from imposing any preexisting condition exclusion. This new protection applies to children who are under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. For individuals age 19 and over, this provision applies for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

Preexisting conditions affect millions of Americans and include a broad range of conditions from heart disease – which affects one in three adults[16] – or cancer – which affects 11 million Americans[17] -- to relatively minor conditions like hay fever, asthma, or previous sports injuries.[18]

Denials of benefits or coverage based on a preexisting condition make adequate health insurance unavailable to millions of Americans. Before the enactment of the Affordable Care Act, in 45 States, health insurance issuers in the individual market could deny coverage, charge higher premiums, and/or deny benefits for a preexisting condition.[19]

These interim final regulations are necessary to amend the Departments' existing regulations to implement this statutory provision, which was enacted by Congress to ensure that quality health coverage is available to more Americans without the imposition of a preexisting condition exclusion.

b. Lifetime and annual limits

As discussed earlier in this preamble, Section 2711 of the PHS Act was added to the Affordable Care Act to prohibit group health plans and health insurance issuers offering group or

[16] American Heart Association. *Heart Disease and Stroke Statistics 2009 Update-at-a-Glance.* http://www.americanheart.org/downloadable/heart/1240250946756LS-1982%20Heart%20and%20Stroke%20Update.042009.pdf
[17] National Cancer Institute. *Cancer Query System: Cancer Prevalence Database*. http://srab.cancer.gov/prevalence/canques.html
[18] Pollitz K, Sorian R. *How Accessible is Individual Health Insurance for Consumers in Less than Perfect Health?* Kaiser Family Foundation, June 2001.
[19] Kaiser State Health Facts. http://statehealthfacts.org/comparetable.jsp?ind=353&cat=7.

individual health insurance coverage from imposing lifetime limits on the dollar value of health benefits. Annual limits also are prohibited, but the statute includes a phase-in of this provision before January 1, 2014, that allows plans and issuers to impose "restricted annual limits" at the levels discussed earlier in this preamble.

These new protections ensure that patients are not confronted with devastating health costs because they have exhausted their health coverage when faced with a serious medical condition. For example, in one recent national survey, ten percent of all cancer patients reported that they reached a benefit limit in their insurance policy and were forced to seek alternative insurance coverage or pay the remainder of their treatment out-of-pocket. [20]

These interim final regulations are necessary to amend the Departments' existing regulations 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. The provisions of the regulations regarding restricted annual limits function as a type of transition rule, providing for staged implementation and helping ensure against adverse impacts on premiums or the offering of health coverage in the marketplace. For more detail about these provisions, see the discussion of PHS Act Section 2711, Lifetime and Annual Limits, in section II.B earlier in this preamble.

c. Rescission

As discussed earlier in this preamble, Section 2712 of the PHS Act was added by the Affordable Care Act to prohibit 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.

[20] USA Today/Kaiser Family Foundation/Harvard School of Public Health. National Survey of Households Affected by Cancer. November 2006.

Prior to the Affordable Care Act, thousands of Americans lost health coverage each year due to rescission. According to a House Energy and Commerce Committee staff memorandum,[21] rather than reviewing medical histories when applications are submitted, if the policyholders become sick and file expensive claims, insurance companies then initiate investigations to scrutinize the details of the policyholder's application materials and medical records, and if discrepancies, omissions, or misrepresentations are found, the insurer rescinds the policies, returns the premiums, and refuses payment for medical services. The Committee found some questionable practices in this area including insurance companies rescinding coverage even when discrepancies are unintentional or caused by others, for conditions that are unknown to policyholders, and for discrepancies unrelated to the medical conditions for which patients sought medical care.

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 they had previously accepted and paid. Rescissions can result in significant financial hardship for affected individuals, because, in most cases, the individuals have accumulated significant medical expenses. 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.[22] This estimate implies there are approximately 10,700 rescissions per year.

These interim final regulations implement the statutory provision enacted by Congress to protect the most vulnerable Americans, those that incur substantial medical expenses due to a

[21] Terminations of Individual Health Insurance Policies by Insurance Companies, Hearing before the House Comm. On Energy and Commerce, Subcommittee on Oversight and Investigations, June 16, 2009) (supplemental memorandum) http://energycommerce.house.gov/Press_111/20090616/rescission_supplemental.pdf.
[22] NAIC Rescission Data Call, December 17, 2009, p.1.

serious medical condition, from financial devastation by ensuring that such individuals do not unjustly lose health coverage by rescission.

d. Patient Protections

As discussed earlier in this preamble, Section 2719A of the PHS Act was added by the Affordable Care Act to require group health plans and health insurance issuers offering group or individual health insurance coverage to ensure choice of health care professionals and greater access to benefits for emergency services. As discussed in more detail below, provider choice is a strong predictor of patient trust in a provider, and patient-provider trust can increase health promotion and therapeutic effects.[23] Studies also have found that patients tend to experience better quality health care if they have long-term relationships with their health care provider.[24]

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 providing the services is a participating network provider, and (2) copayments and coinsurance for out-of-network emergency care not to exceed the cost-sharing requirements that would have been imposed if the services were provided in-network. These provisions will ensure that patients get 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. It also will protect patients from the substantial financial burden that can be

[23] 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).
[24] 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).

imposed when differing copayment or coinsurance arrangements apply to in-network and out-of-network emergency care.

This regulation is necessary to implement the statutory provision enacted by Congress to provide these essential patient protections.

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

a. Summary

As discussed earlier in this preamble, section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA 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 may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act and these interim final regulations prohibit any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704.

In this section, the Departments estimate the likely effects of these interim final regulations. Beginning with the population of individuals age 0-18, the number of individuals potentially affected is estimated in several steps. First, the number of children who have preexisting conditions that might cause them to be excluded from coverage is estimated. Second, a range of take-up rates is used to estimate the number of children who might be newly covered after these interim final regulations are implemented. In addition, the potential cost implications are discussed.

b. Estimated Number of Affected Individuals

In the individual market, those applying for insurance will no longer face exclusions or denials of coverage based on a preexisting condition exclusion if they are under the age of 19. In addition, children covered by non-grandfathered individual coverage with a rider or an exclusion period that excludes coverage for a preexisting condition will gain coverage for that condition. In the group market, participants and dependents who are under 19 years old and have experienced a lapse in coverage will no longer face up to a twelve-month exclusion for preexisting conditions.

The Departments' estimates in this section are based on the 2004-2006 Medical Expenditure Panel Survey Household Component (MEPS-HC) which was projected to 2010 and calibrated to be consistent with the National Health Accounts projections. The analysis tabulated counts and costs for persons under age 19 by age, health status, and insurance status.

There are two main categories of children who are most likely to be directly affected by these interim final regulations: first, children who have a preexisting condition and who are uninsured; second, children who are covered by individual insurance with a rider excluding coverage for a preexisting condition or a preexisting condition exclusion period. For the latter

category, obtaining coverage for the preexisting condition may require terminating the child's existing policy and beginning a new one, because individual health insurance coverage that is a grandfathered health plan is not required to comply with PHS Act section 2704 or these interim final regulations.

It is difficult to estimate precisely how many uninsured children have a preexisting condition that would cause them to be denied coverage for that condition if they were to apply. Information on whether individuals have a preexisting condition for the purpose of obtaining health insurance is not collected in any major population-based survey. In its annual survey on market practices, America's Health Insurance Plans (AHIP) estimated that 429,464 applications for children were medically underwritten, and 20,747, or 4.8 percent, were denied.[25] The survey does not measure the number of applicants who did not make it through an underwriting process, nor does it measure the applicants' prior insurance status, and therefore, while useful, it does not provide direct estimates of the number or proportion of uninsured children who would be denied coverage based on a preexisting condition. Thus, the Departments use proxies for preexisting conditions available in nationally representative surveys to estimate the universe of potentially eligible individuals.

The Departments estimate that in 2010 there are approximately 78.0 million children under the age of 19 in the United States, of whom an estimated 19.4 million report 'fair' or 'poor' health or take three or more prescription medications. The Departments assume that these children have a preexisting condition. Whether or not the statute and these interim final regulations are likely to affect these children depends on their own and their parents' insurance status. Of the 19.4 million children that potentially have a preexisting condition, 10.2 million

[25] AHIP Center for Health Policy Research. *Individual Health Insurance 2009. http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf*

already have employer-sponsored insurance (ESI), 760,000 have individual coverage, and 7.9 million have public or other coverage, leaving 540,000 uninsured children with preexisting conditions.[26] The Departments assume that this group of 540,000 uninsured children with a preexisting condition would be denied coverage for that condition or altogether if they were to apply.

The likelihood that an uninsured child with a preexisting condition will gain coverage due to these interim final regulations will likely vary by the insurance status of the child's parent. As shown in Table 2.1, approximately one-half of the 540,000 uninsured children who the Departments estimate have a preexisting condition live with a parent who is also uninsured and is not offered ESI. An additional 190,000 have a parent who is covered by ESI, and 60,000 children have a parent who was offered ESI but did not accept the offer (and the insurance status of the parent is unknown).

Table 2.1 Estimated number of uninsured children with preexisting conditions, by parent's insurance status, 2010

Parent's insurance status	**Number of children**
Parent has employer-sponsored insurance (ESI)	190,000
Parent offered ESI	60,000
Parent has individual market insurance	10,000
Parent does not have private insurance*	270,000
No parent	20,000
Total **	540,000

* Primarily parents who are uninsured, but also including a small number who have public coverage.
** Total is not the sum of the components due to rounding.

Source: Departments' analysis of MEPS-HC data, 2004-2006, trended forward to 2010.

The group most likely to be affected by these interim final regulations is uninsured children whose parents have purchased non-group coverage, of whom there are an estimated

[26] These estimates are from the Departments' analysis of the 2004-2006 Medical Expenditure Panel Survey, trended forward to 2010.

10,000. These parents have demonstrated a strong preference for coverage by being willing to pay for a non-group premium for themselves, but their child is uninsured. Although the Departments cannot know with any certainty, it is quite plausible that the child is uninsured because the insurer refused to sell coverage to the child due to a preexisting condition. If an individual market insurance policy does not change substantially and retains its grandfather status, the insurer is not required to add a child with a preexisting condition. However, if the parent terminates the existing policy and purchases a new policy (which is quite plausible given the high prevalence of churning in the individual insurance market), then the new policy will be required to cover the child, and a substantial proportion of these children could gain access to coverage due to these interim final regulations.[27]

At the other extreme, roughly 190,000 uninsured children with a preexisting condition have a parent with ESI. It is possible that these children are uninsured because their parents' ESI does not offer dependent coverage. It is also possible that the parent could not afford the employee portion of a family plan premium. These interim final regulations are not likely to have much effect on coverage for children in these circumstances. A very small subset of uninsured children whose parents have ESI could have had to be in a preexisting exclusion period before coverage is provided for services to treat that condition. Under the statute and these interim final regulations, there would no longer be such a period, making coverage desirable. Such children may be affected by this provision.

Approximately 60,000 uninsured children with a preexisting condition have parents who were offered ESI but did not accept that offer. It also seems unlikely that these interim final regulations will have much effect on that group, because almost all of those parents could have

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

chosen to cover themselves, and potentially their child, through ESI in the absence of these interim final regulations.

In between these extremes are the approximately 270,000 uninsured children whose parents are themselves uninsured. Many of these parents have low to moderate income, and many may not be able to afford insurance.[28] However, some of these parents might purchase a policy for their child with a preexisting condition if it were available to them.

While it is relatively easy to hypothesize about the relationship between parental insurance status and the likelihood that a child will be newly covered, it is much more difficult to estimate with any precision the take-up rates for each parental coverage category. Acknowledging substantial uncertainty, based on the discussion above, the Departments' mid-range estimate is that 50 percent of uninsured children whose parents have individual coverage will be newly insured, 15 percent of uninsured children whose parents are uninsured will be newly insured, and that very few children whose parents have ESI, are offered ESI, or who do not live with a parent will become covered as a result of these interim final regulations.[29] For the high-end estimate, the Departments assume that the 50 percent and 15 percent assumptions increase to 75 percent and 20 percent, respectively. For the low-end assumption, they assume that they decrease to 25 percent and 10 percent.

[28] Approximately two-thirds of the uninsured are in families with income below 200 percent of the Federal Poverty Level. Current Population Survey, March 2008.

[29] The Departments researched the literature in an attempt to provide support for the take-up rate assumptions made here. There is a substantial literature on take-up rates among employees who are offered ESI, on take-up rates of public coverage among people eligible for Medicaid and Children's Health Insurance Program, and some work on the purchasing behavior of people who are choosing between being uninsured and buying individual insurance (Aizer, 2006; Kronson, 2009; KFF, 2007; Bernard and Selden, 2006; Sommers and Krimmel, 2008). This work shows that take-up rates are very high for workers who are offered ESI, but that approximately 25 percent of people without ESI purchase individual coverage. This literature can also be used to estimate the price-elasticity of demand, as has been used by the Congressional Budget Office in its estimates of the effects of the Affordable Care Act (http://www.cbo.gov/ftpdocs/87xx/doc8712/10-31-HealthInsurModel.pdf) However, none of this work is very helpful in estimating the level of take-up the Departments should expect as parents are given the opportunity to purchase coverage for their children with preexisting conditions. In the absence of strong empirical guidance, the Departments consulted with experts, used their best judgment, and provide a wide range for our assumptions.

As shown in Table 2.2, the Departments' mid-range estimate is that 51,000 uninsured children with preexisting conditions could gain coverage as a result of these interim final regulations. At the low end of the range, this could be 31,000 and at the high end of the range, it could be 72,000. Given that most ESI already covers children with preexisting conditions, almost all of these children newly gaining coverage are expected to gain individual coverage.[30]

Table 2.2 Estimated number of uninsured children gaining coverage

	Gain Employer-Sponsored Insurance	**Gain Individual Market Insurance**	**Total**
High Take-Up	10,000	62,000	72,000
Medium Take-Up	6,000	45,000	51,000
Low take-Up	2,000	29,000	31,000

Source: Departments' analysis of 2004-2006 MEPS-HC, trended forward to 2010.

The other group of children who will be affected by these interim final regulations is children who already have non-group insurance coverage, but who are covered with a "condition waiver" that excludes coverage or imposes an exclusion period for coverage of a preexisting condition. After the implementation of these interim final regulations, children whose parents purchase individual coverage will not be subject to condition waivers or preexisting condition exclusion periods. The Departments estimate that there are 90,000 children covered by individual insurance with a condition waiver (or with a period during which coverage for a preexisting condition is excluded).[31] The individual market issuers who insure these estimated 90,000 children with a condition waiver may decide to remain grandfathered health plans and

[30] For those parents who turned down an offer of ESI and whose insurance status is not known, the Departments assume that half of the children who takeup coverage join ESI, and half join a private insurance plan in the individual insurance market.

[31] The 2009 AHIP survey for individual coverage estimated that approximately 2.7 percent of children with individual coverage are covered with a condition waiver. This 3 percent estimate was applied to the MEPS-based estimate that there are approximately 3.3 million children covered by individual insurance. A separate analysis of MEPS by the Departments similarly found about 90,000 children with a preexisting condition (defined as being in fair or poor health or taking three or more prescription medications) had a low actuarial value of coverage for their condition.

thus these children will not be directly affected by these interim final regulations. However, the parents of those children could choose to switch from an individual policy that is a grandfathered health plan to a new policy that is not grandfathered, although the premium that they pay for such coverage could increase. Similarly, for those children currently covered but in a preexisting condition exclusion period, curtailing the exclusion period would require the termination of the current plan and purchase of a policy on or after September 23, 2010.

c. Benefits

The benefits of PHS Act Section 2704 and these interim final regulations are expected to amply justify the costs. These interim final regulations will expand and improve coverage for those under the age of 19 with preexisting conditions. This will likely increase access to health care, improve health outcomes, and reduce family financial strain and "job lock," as described below.

Numerous studies confirm that when children become insured, they are better able to access health care. Uninsured children are six times more likely than insured children to lack a usual site of care.[32] By contrast, one year after enrollment in health insurance, nearly every child in one study had a regular physician and the percentage of children who saw a dentist increased by approximately 25 percent.[33] Insured children also experience fewer unmet needs and delays in care. In one study, 37 percent of the children 15 to 19 years of age faced some unmet need or delayed physician care in the prior 6 months, whereas at 12 months after insurance enrollment, only 3.7 percent reported such delays or care deficiencies.[34]

[32] "Children's Health, Why Health Insurance Matters." *Kaiser Commission on Medicaid and the Uninsured*, available at: http://www.kff.org/uninsured/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14132
[33] Ibid.
[34] Keane, Christopher et al. "The Impact of Children's Health Insurance Program by Age." *Pediatrics* 104:5 (1999), available at: http://pediatrics.aappublications.org/cgi/reprint/104/5/1051.

With regular access to health care, children's health and well-being are likely to improve. When children are sick and without health insurance, they may, out of financial necessity, have to forgo treatment; insurance improves the likelihood that children get timely and appropriate health care services.[35] Insured children are less likely to experience avoidable hospital stays than uninsured children[36] and, when hospitalized, insured children are at less risk of dying.[37] When children are insured, it not only improves their health status, but also confers corollary benefits. Children without health insurance may not be allowed to participate in as many physical activities as peers because parents are concerned about the financial impacts of unintentional injury. One study determined that 12 percent of uninsured children had various activity restrictions (e.g., related to sports or biking). However, almost all of these restrictions were removed once they gained insurance.[38] And health insurance and access to care improve school attendance. An evaluation of an initiative designed to connect children to Healthy Kids, an insurance program piloted in Santa Clara County, California for children in low-income families, found that the proportion of children missing three or more school days in the previous month decreased from 11 percent among non-enrollees to 5 percent after enrollment in the insurance program.[39]

In addition to their benefits relating to access to care, health, and well-being of children, these interim final regulations are likely to lower families' out of pocket health care spending. Some families would face the possibility of paying high out-of-pocket expenses for health care

[35] Uninsured children are at least 70 percent more likely than insured children to not receive medical care for common childhood conditions like sore throats, ear infections, and asthma. Ibid.
[36] Ibid.
[37] Bernstein, Jill et al. "How Does Insurance Coverage Improve Health Outcomes?" *Mathematica Policy Research* (2010), available: http://www.mathematica-mpr.com/publications/PDFs/Health/Reformhealthcare_IB1.pdf
[38] "Children's Health, Why Health Insurance Matters." *Kaiser Commission on Medicaid and the Uninsured*, available at: http://www.kff.org/uninsured/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14132
[39] Howell, Embry and Trenholm, Christopher "Santa Clara County Children's Health Initiative Improves Children's Health." *Mathematica Policy Research and The Urban Institute* (2007), available at: http://www.mathematica-mpr.com/publications/PDFs/CHIimproves.pdf

for children under 19 who could not obtain insurance because of a preexisting condition. Further, expanded insurance coverage should reduce the number of medical bankruptcies.[40] In cases where medical expenses are substantial, families may no longer need to spend down their assets in order to qualify for Medicaid and other public assistance programs. Approximately 34 States offer Medicaid eligibility to adults and children who spend-down to State-established medically needy income limits.[41] Eight percent of Medicaid beneficiaries qualify via spend-down yet this group accounts for a disproportionately high percentage of Medicaid spending nationally (14 percent), due to the fact that coverage kicks in when individuals' medical costs are high.[42] Despite the fact that medically needy populations become eligible on account of onerous medical bills, this group is especially vulnerable to losing coverage because States are not *required* to cover this group. For example, in 2003, when Oklahoma eliminated its medically needy program due to a budget shortfall, an estimated 800 children lost coverage.[43] Such coverage interruptions likely contribute to higher rates of uncompensated care – the primary source for which is Federal funding.[44] Reduced reliance on these programs under these interim final regulations will benefit State and Federal governments and, by extension, taxpayers.

In addition, these interim 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 their children.[45] For example, under the Affordable Care Act and these interim

[40] Himmelstein, D., Warren, E., Thorne, D., and Woolhandler, S. Illness and Injury as Contributors to Bankruptcy, *Health Affairs* W5-63, February 2 (2005); Himmelstein, D., Thorne, D., Warren, E., Woolhandler, S. Medical Bankruptcy in the United States, 2007: The Results of a National Study, *The American Journal of Medicine* June 4 (2009).
[41] http://www.statehealthfacts.org/comparereport.jsp?rep=60&cat=4
[42] Page 4: http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14325
[43] Page 4: http://www.nashp.org/sites/default/files/shpmonitor_medicallyneedy.pdf
[44] Page 4: http://www.kff.org/uninsured/upload/The-Cost-of-Care-for-the-Uninsured-What-Do-We-Spend-Who-Pays-and-What-Would-Full-Coverage-Add-to-Medical-Spending.pdf
[45] A CEA report suggests that the overall cost of job-lock could be $3.7 billion annually, which is about 10 percent of affected workers wages. While these interim final regulations may only have an impact on a small percentage of

final regulations, someone currently insured through the group market with less than 18 months of continuous coverage may be more willing to leave her job and become a self-employed entrepreneur if she has a child under age 19 with a preexisting condition, because her child now will be able to obtain immediate coverage for the preexisting condition in the individual market. 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 he would not have to worry that his child's preexisting condition would be excluded for up to 12 months.[46] While the total reduction in job-lock may be small, the impact on those families with children with preexisting conditions may be significant. The effect of these interim final regulations on job-lock is discussed further in the summary section below.

Executive Order 12866 explicitly requires agencies to take account of "distributive impacts" and "equity." Requiring health insurers to provide coverage to children with preexisting conditions will, as described below, result in a small increase in premium for relatively healthy adults and children, and a large increase in health and financial security for children with preexisting conditions and their parents. This transfer is a meaningful increase in equity, and is a benefit of these interim final regulations.

d. Costs and Transfers

Children with preexisting conditions have high health care costs – approximately three

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all individuals affected by job-lock it could still have a large dollar impact for those affected. Council of Economic Advisors Report, The Economic Case for Health Reform (June 2009), at http://www.whitehouse.gov/assets/documents/CEA_Health_Care_Report.pdf.

[46] A 2006 study found no evidence that the introduction of HIPAA, which reduced preexisting condition exclusions, had any impact on job lock, but HIPAA still allows a 12-month preexisting condition exclusion meaning that for conditions that need immediate care someone could still effectively be uninsured for up to a year. In contrast, the provisions of the statute and these interim final regulations would not allow any preexisting condition exclusion. *See e.g.*, Paul Fronstin, *Health Insurance Portability and Job Lock: Findings from the 1998 Health Confidence Survey*, Employee Benefit Research Institute Notes, Volume 19, Number 8, pages 4-6 (Aug. 1998) and Anna Sanz-de-Galdeano, *Job-Lock and Public Policy: Clinton's Second Mandate*, Industrial and Labor Relations Review, Volume 59, Number 3, pages 430-37 (Apr. 2006).

times the average for those without such conditions.[47] Although children with preexisting conditions have higher health care costs than healthier children, among children with preexisting conditions, those who are uninsured have expenditures that are somewhat lower than the average for all children with preexisting conditions. Therefore, it is expected that when uninsured children obtain coverage, there will be additional demand for and utilization of services. There will also be 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.

As shown above in Table 2.2, the Departments estimate that approximately 2,000 to 10,000 children whose parents have ESI or an offer of ESI will be newly covered in the group market. Because few children are likely to be newly covered in the group market, the estimated costs and transfers are extremely small, on the order of hundredths of a percent.

The Departments expect that these interim final regulations will have a larger effect on the number of children covered in the individual market, resulting in new coverage for between 29,000 and 62,000 children. Medical expenses for these newly covered children are likely to be greater than for the average child covered by individual insurance. The Departments' analysis also assumes that children with preexisting conditions gaining insurance under these interim final regulations will have greater health needs than the average uninsured child with a preexisting condition. This assumption concerning adverse selection is common to most analyses of purchasing behavior in the individual insurance market.

In the majority of States that do not require community rating, much of the additional cost of care for newly-covered children with preexisting condition is likely to be borne by the parents who purchase coverage for their children. Based on discussions with industry experts, it

[47] From the Departments' analysis of MEPS data.

appears that even in the absence of community rating, it is rare for an insurer to charge more than twice the standard rate for someone in poor health. The Departments' analysis assumes that in non-community rated States, the parents of newly insured children will pay a premium that is equal to twice the standard rate, and the remainder of the additional costs will be spread to other policy holders in the individual market.[48] However, with the enactment of the Affordable care Act and the issuance of these interim final regulations, rating practices in the insurance industry could certainly change, lending uncertainty to this estimate. In the approximately twenty States that require adjusted community rating or rating bands in the individual market, the Departments' analysis assumes that all of the additional costs of newly covered children will be spread across policies in the individual market that are not grandfathered health plans.[49] Making these assumptions, the estimated increase in premiums is 1 percent or less in community rated States, and approximately one-half of one percent in States without community rating.

Finally, for the estimated 90,000 children with existing individual coverage that excludes coverage for the preexisting condition or requires an exclusion period before coverage for that condition begins, the Departments assume that many of these children will receive coverage for their condition(s). Because their existing individual policies could be grandfathered, the parents of these children may need to purchase new policies in order to gain coverage for their children's condition without a waiver. Children in a preexisting condition exclusion period in particular will need to terminate their current policy and purchase a new one in order to take advantage of the elimination of any preexisting condition exclusion period. Of note, the Departments estimate

[48] The Departments assume that in non-community rated States, parents purchasing individual coverage for a child with a preexisting condition will be charged a rate equal to 200 percent of the standard rate for a child, because it is rare for insurers to charge more than this amount, but it seems unlikely they will charge less. To the extent that the estimated expenditures for newly covered children are above the premium that the Departments assume will be charged, the analysis assumes that the difference will be spread over all policies in the individual market.

[49] http://www.statehealthfacts.kff.org/comparetable.jsp?ind=354&cat=7

that turnover in the individual market is between 40 percent and 70 percent per year.[50] Therefore, in a few years, most children who would have been covered with a condition waiver in the absence of these interim final regulations are expected to be in new policies that are not grandfathered health plans in any case.

The Departments analyzed expenditures for the approximately 90,000 children who reported fair or poor health, or who were taking three or more prescription medications, and for whom insurance covered only a small portion of spending for one or more medical conditions. Total spending for these 90,000 children was not much different than spending for the children who did not appear to have a preexisting condition waiver, although less of the spending was covered by private insurance, and more of it was paid for out-of-pocket or by other sources.[51]

Similar to the expectations for newly covered children in the individual market, in States that require rating bands or some form of community rating, much of the additional cost for eliminating condition waivers will be spread across the insured population, while in States without rating restrictions, much of the additional costs will be borne by the parents who purchase the coverage. However, the estimate that insured benefits per child will increase by a relatively modest amount suggests that even in States with community rating, the cost and transfer effects will be relatively small, at most a few tenths of a percent over the next few years.

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 that go into effect at the same time. For example, under the current

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

[51] The Departments' analysis used MEPS data to identify approximately 90,000 children with individual coverage for whom insurance coverage for one or more conditions was extremely low – averaging 10 percent of covered expenditures, compared to approximately 80 percent for other children. The analysis assumes that these children were subject to a preexisting condition waiver, and then assumes that when these waivers are eliminated, the expenditures that are not covered by insurance in the MEPS data will now be shifted to insurance.

guaranteed renewability protections in the individual market, if a child with a preexisting condition is now able to obtain coverage on a parental plan, he or she can potentially stay on that plan until age 26. As another example, the Affordable Care Act will require non-grandfathered health plans to provide recommended preventive services at no cost-sharing. This will amplify the benefits of coverage for newly insured children with preexisting conditions. Therefore, the Departments cannot provide a more precise estimation of either the benefits or the costs and transfers of this provision.

3. PHS Act Section 2711, No Lifetime or Annual Limits (26 CFR 54.9815-2711T, 29 CFR 2590.715-2711, 45 CFR 147.126)

a. Summary

As discussed earlier in this preamble, section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. The statute also provides a special rule allowing "restricted annual limits" with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute specifies that a plan or issuer may impose annual or lifetime per-individual limits on specific covered benefits that are not essential health benefits to the extent that such limits are permitted under Federal or State law.

For purposes of establishing a restricted annual limit on the dollar value of essential health benefits, the statute provides that in defining the term restricted annual limit, the Departments "ensure that access to needed services is made available with a minimal impact on

premiums."[52] Based on this Congressional directive, the interim final regulations allow annual limits on the dollar value of benefits that are essential health benefits of no less than $750,000 for plan years (in the individual market, policy years) beginning on or after September 23, 2010, but before September 23, 2011; $1.25 million for plan years (in the individual market, policy years) beginning on or after September 23, 2011, but before September 23, 2012; and $2 million for plan years (in the individual market, policy years) beginning on or after September 23, 2012, but before January 1, 2014. For plan years (in the individual market, policy years) beginning January 1, 2014, no annual limits may be placed on essential health benefits.

The statute and these interim final regulations relating to the prohibition on *lifetime* limits generally apply to all group health plans and health insurance issuers offering group or individual health insurance coverage, whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on *annual* limits, including the special rules for plan years beginning before January 1, 2014, generally apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.

b. Estimated Number of Affected Entities

In 2009, the latest data available indicates that both the incidence and amount of lifetime limits vary by market and plan type (e.g., HMO, PPO, POS). Table 3.1 displays the prevalence of lifetime limits for large employer, small employer and individual markets by plan type. Sixty-three percent of large employers had lifetime limits; 52 percent of small employers had lifetime

[52] PHS Act section 2711(a)(2) as added by Section 1001(5) of the Affordable Care Act and amended by section 10101(a) of such Act.

limits and 89 percent of individual market plans had lifetime limits. HMO plans are the least likely to have a lifetime limit with only 37 percent of large employer HMO plans having a limit, 16 percent of small employer HMO plans having a limit and 23 percent of individual HMO plans having a limit. The generosity of the limit also varies, with 45 percent of all large employer plans imposing a lifetime limit of $2,000,000 or more; 39 percent of small employers' plans imposing a limit of $2,000,000 or more and 86 percent of individual market plans imposing a limit of $2,000,000 or more. Note that small employers are more likely than large employers to offer HMOs that tend not to have lifetime limits, but when small businesses offer plans with lifetime limits, the maximum limit tends to be lower than those in large firms.[53]

Table 3.1: Prevalence of Lifetime Limits

Market	Prevalence of Limit	Number of Enrollees
Large Group		
Under $1,000,000	1%	1,000,000
$1,000,000 - $2,000,000	18%	18,700,000
$2,000,000 or higher	45%	46,600,000
No Limit	37%	38,300,000
Small Group		
Under $1,000,000	1%	500,000
$1,000,000 - $2,000,000	12%	6,300,000
$2,000,000 or higher	39%	20,500,000
No Limit	48%	25,200,000
Individual		
Under $1,000,000	2%	200,000
$1,000,000 - $2,000,000	1%	100,000
$2,000,000 or higher	86%	8,400,000
No Limit	11%	1,100,000

Source: *Large and Small Employer Health Plan Enrollment: and Lifetime Maximum Exhibit 5.2 and Exhibit 13.12, respectively, Employer Health Benefits: 2009 Annual Survey. Washington, DC: Henry J. Kaiser Family Foundation and Health Research & Educational Trust, (September 2009). Individual Health Plan Enrollment and Lifetime Maximum: Table 10 and Table 17, respectively, AHIP Center for Policy Research Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability, and Benefits*

[53] *Employer Health Benefits: 2009 Annual Survey*. Washington, DC: Henry J. Kaiser Family Foundation and Health Research & Educational Trust, (September 2009).

There are scant data on annual limits on which to base this impact analysis. Table 3.2 displays the prevalence of annual limits by market, plan type and amount of the limit. Only 8 percent of large employers, 14 percent of small employers and 19 percent of individual market policies impose an annual limit and thus would be directly impacted by these interim final regulations.[54] In the first year of implementation (beginning September 23, 2010), it is estimated that less than 0.08 percent (less than one tenth of one percent) of large employer plans, approximately 2.6 percent of small employer plans, and 2.3 percent of individual plans would have to raise their annual limit to $750,000.[55] This first-year increase in annual limits would potentially affect an estimated 1,670,000 persons across the three markets. The second year of the phase-in, beginning September 23, 2011, would affect additional plans and policies, requiring a cumulative 0.7 percent of large employer plans, 3.9 percent of small employer plans, and 5.3 percent of individual policies to increase their annual limit to $1,250,000. The second-year increase in annual limits would affect an estimated 3,278,250 persons across the three markets. The third and final year of the phase-in period (beginning on September 23, 2012) would affect additional plans and policies requiring a cumulative 2.4 percent of large employer plans, 8.1 percent of small employer plans and 14.3 percent of individual policies to increase their annual limit to $2 million. The third-year increase in annual limits would affect an estimated 8,104,500

[54] There is limited survey data on annual total benefit limits. The data utilized in these analyses are derived from data collected by Mercer's Health and Benefits Research Unit for their 2005, 2008 and 2009 National Survey of Employer-Sponsored Health Plans. For employer plans, the Mercer data provides prevalence information for PPOs and HMOs, and median annual limit levels for PPOs, split by small and large employer plans. In order to generate a plausible baseline of annual benefit maximums, broken by level of maximum, the reported percentages of employer plans that had annual maximums were spread into four intervals broken at $500k, $1 million, and $2 million. For PPOs and HMOs, the data were spread using the dispersion observed in lifetime benefit maximums (using data from the KFF/HRET employer surveys), and the distribution was constrained to be consistent with the Mercer reported median values for annual maximums. For annual benefit limits in individual coverage the relationship observed between AHIP's reported lifetime benefit maximum levels and the KFF/HRET employer lifetime benefit maximums was used to generate corresponding distributions from the synthesized employer annual limits.

[55] These figures and the ones that follow in this paragraph are estimated from Tables 2.2 and 2.3 by assuming a uniform distribution within each cell.

persons across the three markets. Note that the estimated number of plans and people affected are upper-bound estimates since they do not take into account grandfathered health plans and plans that receive a waiver from the annual limits policy.

Table 3.2 Percent of plans employing annual limits in each market

Annual Limit	Large Employer	Small Employer	Individual
Under $250,000	*	0.4%	0.4%
$250,000 - 499,999	*	1.3%	1.2%
$500,000 – 999,999	*	1.7%	1.6%
$1,000,000 – 1,999,999	2.3%	5.5%	12.0%
$2,000,000 plus	5.8%	5.5%	3.8%
Total	8.2%	14.4%	19.0%

* Less than 0.1%

Source: *The data are derived from data collected by Mercer's Health and Benefits Research Unit for their 2005, 2008 and 2009 National Survey of Employer-Sponsored Health Plans. For employer plans, the Mercer data provides prevalence information for PPOs and HMOs, and median annual limit levels for PPOs, split by small and large employer plans. In order to generate a plausible baseline of annual benefit maximums, broken by level of maximum, the reported percentages of employer plans that had annual maximums were spread into four intervals broken at $500k, $1 million, and $2 million. For PPOs and HMOs, the data were spread using the dispersion observed in lifetime benefit maximums (using data from the KFF/HRET employer surveys), and the distribution was constrained to be consistent with the Mercer reported median values for annual maximums. For annual benefit limits in individual coverage the relationship observed between AHIP's reported lifetime benefit maximum levels and the KFF/HRET employer lifetime benefit maximums was used to generate corresponding distributions from the synthesized employer annual limits*

Table 3.3 Number of persons subjected to annual limits in each market

Annual Limit	Large Employer	Small Employer	Individual	Total
Under $250,000	15,000	225,000	38,000	278,000
$250,000 - 499,999	45,000	675,000	115,000	835,000
$500,000 – 999,999	60,000	900,000	153,000	1,113,000
$1,000,000 – 1,999,999	2,389,000	2,869,000	1,177,000	6,435,000
$2,000,000 plus	6,041,000	2,869,000	377,000	9,287,000
Total	8,550,000	7,538,000	1,860,000	17,948,000

Source: *The data are derived from data collected by Mercer's Health and Benefits Research Unit for their 2005, 2008 and 2009 National Survey of Employer-Sponsored Health Plans. For employer plans, the Mercer data provides prevalence information for PPOs and HMOs, and median annual limit levels for PPOs, split by small and large employer plans. In order to generate a plausible baseline of annual benefit maximums, broken by level of maximum, the reported percentages of employer plans that had annual maximums were spread into four intervals broken at $500k, $1 million, and $2 million. For PPOs and HMOs, the data were spread using the dispersion observed in lifetime benefit maximums (using data from the KFF/HRET employer surveys), and the distribution was constrained to be consistent with the Mercer reported median values for annual maximums. For annual benefit limits in individual coverage the relationship observed between AHIP's reported lifetime benefit maximum levels and the KFF/HRET employer lifetime benefit maximums was used to generate corresponding distributions from the synthesized employer annual limits*

Fear and anxiety about reaching annual or lifetime limits on coverage is a major concern among Americans who have health insurance. At the same time, the data suggest that relatively few individuals actually reach their policies' annual and lifetime limits. Thus, while such limits are relatively common in health insurance, the numbers of people expected to exceed either an annual or lifetime limit is quite low. The estimates provided in Table 3.4 provide a high and low range of the number of people who would hit such limits. Such a range is necessary because of the tremendous uncertainty around high-cost individuals. First, data are sparse, given that high-cost individuals lie at the tail of statistical cost distributions. The Departments attempted to extrapolate characteristics of the high-cost population who would be affected by these interim final regulations using several data sources. Second, data on per-capita cost is available on a year-by-year basis, and not on a lifetime basis. Assumptions were necessary to convert annual costs into lifetime costs, including considerations of how current spending could be related to future spending.[56]

Considering these caveats, Table 3.4 illustrates that raising the restriction of annual limits to $2 million by 2013 would extend additional coverage to 2,700 to 3,500 people per year.[57] The elimination of lifetime limits would extend coverage to an estimated 18,650 to 20,400 people who would be expected to exceed a lifetime limit during a calendar year.

Table 3.4 Percent and number of persons expected to exceed a lifetime or annual limit

	Projected to ever exceed limit	
Current Lifetime Limit	**Percentage**	**Number**
Under $1,000,000	0.03- 0.06%	550-1,050

[56] To estimate the conditional premium impact of moving a given plan with a given annual benefit maximum to a higher benefit maximum, the percentage change in estimated benefit rates (percent of medical spending that the plan pays for as benefits) based on simulated benefit payments for such coverage was used. The underlying assumed medical spending profile was drawn from MEPS-HC person level spending data, calibrated to National Health Account levels, with the shape of the distribution modified based on high-cost claims data from the Society of Actuaries. The conditional premium increases were then applied to the fractions of plans in each of the three market segments by level of current annual limits to calculate the aggregate increase in premiums for the possible option.

[57] Numbers in this paragraph calculated from Table 2.4 may differ due to rounding.

$1,000,000 to $1,999,999	0.02%	4,500-5,000
$2,000,000 plus	0.02%	13,600-14,350
Current Annual Limit		
Under $250,000	0.19-0.23%	550-650
$250,000 to $499,999	0.08-0.10%	650-850
$500,000 to $999,000	0.03-0.06%	350-700
$1,000,000 to $1,999,999	0.02%	1,150-1,300
$2,000,000 or more	0.01-0.02%	750-1,750

Source: *Estimates of the expected percentage of the insured population who would exceed a limit are based on an analysis of the MEPS-HC expenditure data supplemental with adjusted insurer claims from the Society of Actuaries large claims database; http://www.soa.org/files/pdf/Large_Claims_Report.pdf. Numbers of people rounded to the nearest 50.*

c. Benefits

Annual and lifetime limits exist in the individual, small group and large group health insurance markets. These limits function as caps on how much an 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,[58] which are typically very serious. For example, one recent survey found that 10 percent of cancer patients reached the limit of what insurance would pay for treatment.[59] The same survey also found that 25 percent of cancer patients or their family members used up all or most of their savings, 13 percent were contacted by a collection agency, and 11 percent said they were unable to pay for basic necessities like food and housing as a result of the financial cost of dealing with cancer. By prohibiting lifetime limits and restricting annual limits, these interim final regulations will help families and individuals experiencing financial burdens due to exceeding the benefit limits of their insurance policy. By ensuring and

[58] An April 2008 study by Milliman "2008 U.S. Organ and Tissue transplant cost estimates", found that the average one year billed charges related to a heart transplant averaged $787,000 while a liver transplant averaged $523,400. The lifetime costs for the treatment chronic disease such as of HIV infection have been well documented with one estimate of $618,000 (*Med Care* 2006;44: 990–997).

[59] See "National Survey of Households Affected by Cancer." (2006) accessed at http://www.kff.org/kaiserpolls/upload/7591.pdf

continuing coverage, these interim final regulations also reduce uncompensated care, which would otherwise increase premiums of the insured population through cost-shifting, as discussed in more detail in section IV.B.6 later in this preamble.

These interim final regulations will also improve access to care. Reaching a limit could interrupt or cause the termination of needed treatment, leading to worsening of medical conditions. Moreover, those with medical debt are more likely to skip a needed test or treatment, and less likely to fill a prescription or visit a doctor or clinic for a medical issue.[60] The removal and restriction of benefit limits helps ensure continuity of care and the elimination of the extra costs that arise when an 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. Lack of insurance coverage leads to additional mortality and lost workplace productivity, effects that would be amplified for a sicker population such as those who would reach a benefit limit.[61] By ensuring continuation of coverage, these interim final regulations benefit the health and the economic well-being of participants, beneficiaries, and enrollees.

These interim final regulations also benefit those without an alternative source of health coverage in the group health insurance market. Under HIPAA rules, when an individual exceeds a limit and loses coverage, that individual has a special enrollment right. If his or her plan offered multiple benefit packages or a spouse has access to ESI, the individual could enroll in the coverage, although it might lead to a change in providers and less generous coverage. Those without an alternative option would lose coverage, and the history of high medical claims and presence of preexisting conditions could make health insurance in the individual market

[60] Seifert, Robert W., and Mark Rukavina. "Bankruptcy Is The Tip Of A Medical-Debt Iceberg." *Health Affairs* Web Exclusive (2006)

[61] See Institute of Medicine.(2003). *Hidden Costs, Value Lost: Uninsurance in America.* Washington, DC: National Academy Press; and Institute of Medicine. (2002). *Care Without Coverage: Too Little, Too Late.* Washington, DC: National Academy Press.

impossible. Under these interim final regulations, people will no longer be treated differently depending on whether they have an alternative source of coverage.

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 these interim final regulations. Prohibiting lifetime limits and restricting annual limits assures that insurance will perform the function for which it was designed – namely, protecting health and financial well being for those most in need of care. This represents a meaningful improvement in equity, which is a benefit associated with these interim final regulations.

d. Costs and Transfers

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 will increase the actuarial value of the insurance coverage for affected plans and policies if no other changes are made to the plan or policy. Issuers and plans in the group market may choose 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 will be 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 could result in lower profits or higher prices for the employer's goods or services. Given the relatively small proportion of people who exceed the benefit limits in the current group markets,

the Departments anticipate such transfers to be minimal when spread across the insured population (at a premium increase of one-half of a percent or less for lifetime limits and one-tenth of a percent or less for annual limits), compared with the substantial benefit rendered to individual high-cost enrollees. However, as this discussion demonstrates, there is substantial uncertainty in data and in the choices plans will decide to make in response to these interim final regulations, preventing more precise estimations of effects.

In the individual market, where policies are individually underwritten with no rating bands in the majority of States, the Departments expect the added premium cost or other benefit changes to be largely borne by the individual policyholder. As discussed in the impact analysis for Section 2704, if costs exceed 200 percent of the standard rate, some of the additional costs could be spread across the insurance market. In the 20 States with modified community rating, issuers could spread the increased costs across the entire individual market, leading to a transfer from those who would not incur high medical costs to those who do incur such costs. However, as with the group market, such a transfer is expected to be modest, given the small numbers of people who would exceed their benefit limit. The Departments estimate 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. Also, given the wide variation in State insurance markets, a more precise estimation is not possible, and the premium impact would be even less in the majority of States that allow underwriting in the individual insurance market.

It is worth noting that the transfers discussed above will be significantly mitigated by the associated expansion of coverage that these interim final regulations create. The Departments

expect, as a result of the gradual elimination of annual limits and the immediate elimination of lifetime limits, fewer people will be left without protection against high medical costs. This will lead fewer individuals to spend down resources and enroll in Medicaid or receive other State and locally funded medical support. It can be anticipated that such an effect will be amplified due to the high-cost nature of people who exceed benefit limits. As a result, there will be a reduction in Medicaid, State and local funded health care coverage programs, as well as uncompensated care, all of which would otherwise raise taxes and/or premiums for the larger population. Unfortunately, data around these high-cost individuals is limited, preventing the Departments from quantifying these benefits at the present time.

Additional uncertainty prevents more precise estimation of the benefits and impacts of this provision. As discussed in the impact analysis for Section 2704, there are interactive effects of the various provisions in these interim final regulations which cannot be estimated. For example, prohibiting rescissions and lifetime limits could mean that someone who would have had a policy rescinded now maintains coverage, and also maintains coverage beyond a previous lifetime limit. Moreover, it is important to note that the estimates presented here, by necessity, utilize "average" experiences and "average" plans. Different plans have different characteristics of enrollees, for example in terms of age or health status, meaning that provisions such as eliminating lifetime or restricting annual limits could affect them differently. This also means that average impacts of the various provisions in these interim final regulations or others cannot simply be added to obtain a total impact, since a plan may be affected by one provision but not another. Moreover, plans and issuers will consider these impacts when making decisions about whether or not to make other changes to their coverage that could affect their grandfather status – a consideration that is pertinent in the case of restricted annual limits, which do not apply to the

grandfathered individual market. This further compounds any precise calculation of benefits and costs.

e. Enrollment Opportunity

These interim final regulations provide an enrollment (or, in the case of the individual market, reinstatement) opportunity for individuals who reached their lifetime limits in a group health plan or health insurance coverage and remain otherwise eligible for the coverage. In the individual market, the reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in an individual health insurance family policy while other family members remain in coverage. Such enrollment opportunity would generate a total hour burden of 3,800 hours and a cost burden of $21,000, as detailed in the Paperwork Reduction Act section.

f. Alternatives

PHS Act section 2711(a)(2) requires the Departments to "ensure that access to needed services is made available with a minimal impact on premiums." Accordingly, the Departments undertook an analysis of different restricted annual limit thresholds to study the issue, taking into consideration several factors: (1) the current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited. In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access

to essential health benefits, the Departments decided to adopt a three-year phased approach for restricted annual limits.

As discussed above, it is important to note that it is difficult to predict exactly how plans and issuers will respond under the new regulations. Annual or lifetime limits on benefits help control risk and costs, and the elimination of a lifetime limit or a possible increase in an annual limit may lead plans and issuers to alter benefit design (such as increasing cost-sharing), and/or raise premiums. The Departments cannot determine which option or combination of options plans and issuers will choose. Therefore, it is very difficult to measure the impact on premiums due to the elimination of lifetime limits and a maximum annual limit. This uncertainty is compounded by the data uncertainties discussed earlier in section IV.B.2.b of this preamble.

Given the above data limitations, the Departments modeled the impact on premiums of increasing the annual limits for plans that currently have annual limits, assuming that the only reaction to a required increase in annual limits would be an increase in premiums. Because some plans may choose to avoid or offset the potential premium increase by increasing cost sharing, tightening the network of providers, adopting cost savings tools, or making other plan changes, the modeled premium impacts represent the high-end of the possible increases in premiums.

The Departments modeled a range of options and ways to implement a restricted annual limit. Two of the options considered were setting the annual restricted limit on essential benefits at $1 million or at $2 million. The higher the limit is set, the fewer the people that would exceed the limit and experience a gap in insurance coverage. However, plans with current low limits could see increases in costs and potentially premiums because the proportion of claims covered by the plans would increase. One final issue to consider is that for plan years (in the individual market, policy years) beginning after January 1, 2014, all group plans and non-grandfathered

individual policies will be required to remove annual limits. A low annual limit until 2014 would offer less protection to those with medical expenses exceeding the limit, and could result in an increase in premiums in 2014 (although a variety of other changes that will be implemented in 2014 could be expected to result in lower premium increases in most States). Therefore, a stepped approach allowing the restricted annual limit to be phased in over time seemed to be the fairest approach and most likely to result in a minimal impact on premiums, so it was selected.

Table 3.5 demonstrates premium impacts at different annual limit thresholds, and Table 3.4 above demonstrates the numbers of people expected to exceed different annual limit thresholds. The Departments chose to set the restricted annual limit relatively low in the first year, and to then increase the limit up to $2 million over the three-year period. This phased approach was intended to ease any increases in premiums in any one year, particularly for plans with low initial annual limits, and to help group plans and non-grandfathered individual policies transition to no annual limits starting in 2014. With this approach, a threshold of $750,000 was associated with a 5.1 percent premium impact for plans with very low annual limits of $250,000, but it is anticipated that these plans comprise only less than one-half of one percent of the market. On the other hand, raising the restricted annual limits to $2,000,000 under these interim final regulations could be expected to help an estimated 2,700 to 3,500 people[62] who would no longer exceed their annual limit, ensuring financial protection to those who have high medical claims.

It is important to note that these interim final regulations also provide that the Secretary of HHS may establish a waiver program under which issuers or plans may assert that adhering to the restricted annual limit provisions of these interim final regulations would result in a significant decrease in access to benefits or a significant premium increase. The Departments

[62] Numbers calculated from Table 3.4 may differ due to rounding.

provided for this waiver in order to prevent the loss of coverage for enrollees in low-benefit plans (for example, "mini-med" plans) that have low annual limits. While the impact of this policy is not quantified, it, too, is intended to mitigate any unintended consequences given the paucity of data on the incidence and prevalence of annual limits in the markets today.

Table 3.5 Estimated premium impacts for a plan moving to a new annual limit

Current Limit	People Subject to Current Limit	New Limit				
		$500k	**$750k**	**$1 million**	**$1.5 million**	**$2 million**
$250k	278,000	3.7%	5.1%	6.1%	6.2-6.4%	6.2[63]-6.6%
$500k	835,000		1.4%	2.3%	2.4-2.6%	2.4-2.8%
$750k	1,113,000			1.0%	1.0-1.2%	1.0-1.5%
$1 million	6,435,000				0.1-0.3%	0.1-0.5%
$1.5 million	9,287,000					0.04-0.2%

Source: *Premium estimates are calculated based MEPS-HC supplemented with the Society of Actuaries Large Claim Database – To estimate the conditional premium impact of moving a given plan with a given annual benefit maximum to a higher benefit maximum, the percentage change in estimated benefit rates (percent of medical spending that the plan pays for as benefits) based on simulated benefit payments for such coverages was used. The underlying assumed medical spending profile was drawn from MEPS-HC person level spending data, calibrated to National Health Account levels, with the shape of the distribution modified based on high-cost claims data from the Society of Actuaries. The conditional premium increases were then applied to the fractions of plans in each of the three market segments by level of current annual limits to calculate the aggregate increase in premiums for the possible option. For the low impact estimates, the distributions were then adjusted only for the expected marginal loading impact of using commercial reinsurance for many of the smaller carriers. For the high impact estimates, the distributions were also adjusted to reflect possible underestimation of the tails of the expenditure distribution once coverage of unlimited benefit levels was required. The adjustments were set at levels that generated aggregate impacts that were conservative relative to estimates from PricewaterhouseCoopers' March 2009 study of lifetime limits for the National Hemophilia Foundation.*

4. PHS Act Section 2712, Rescissions (26 CFR 54.9815-2712T, 29 CFR 2590.715-2712, 45 CFR 147.128)

a. Summary

As discussed earlier in this preamble, PHS Act Section 2712 provides 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 from the individual covered under the plan or coverage

[63] If a second decimal place were included, the lower end of the range in this column would be greater than the lower end of the range in the $1.5 million column.

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. These interim 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.[64] The notice must be provided regardless of whether the rescission is 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.

PHS Act Section 2712 and these interim 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 court-made Federal common law 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). Each styled a remedy looking to State law, the majority of Federal courts or the Restatement of Contracts. According to a House Energy and Commerce Committee staff memorandum,[65] rather than reviewing medical histories when applications are submitted, some insurers engage in "post-claims underwriting." Under this practice, if the policyholders become sick and file expensive claims, the insurance companies initiate investigations to scrutinize the details of the policyholder's application materials and medical records, and if discrepancies, omissions, or misrepresentations are found, the insurer rescinds the policies, returns the premiums, and refuses payment for medical services. The

[64] Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

[65] *Terminations of Individual Health Insurance Policies by Insurance Companies, Hearing before the House Comm. On Energy and Commerce, Subcommittee On Oversight and Investigations*, June 16, 2009 (supplemental memorandum), *at: http://energycommerce.house.gov/Press_111/20090616/rescission_supplemental.pdf.*

Committee found some questionable practices in this area including insurance companies rescinding coverage even when discrepancies are unintentional or caused by others, for conditions that are unknown to policyholders, and for discrepancies unrelated to the medical conditions for which patients sought medical care. According to the Committee, the current regulatory framework governing the individual insurance market in this area is a haphazard collection of inconsistent State and Federal laws. Protections for consumers and enforcement actions by regulators vary depending on where individuals live. Because of these varying standards, many patients lack adequate protections against rescission, prompting the need for and benefits from this rule.

When a coverage rescission occurs, an individual's health insurance coverage is retroactively cancelled, which means that the insurance company is no longer responsible for medical care claims that they had previously accepted and paid. Rescissions can result in significant financial hardship for affected individuals, because, in most cases, the individuals have accumulated significant medical expenses.

b. Estimated Number of Affected Entities

The Departments assume that these interim final regulations will have their largest impact on the individual insurance market, because group health coverage rarely is rescinded.[66] By creating a new Federal standard governing when policies can be rescinded, the Departments expect these interim final regulations to potentially affect the approximately 17 million non-elderly individual health insurance policy holders and their dependents in the individual health insurance market.[67] In addition, approximately 490 health insurance issuers offering coverage in the individual health insurance market who currently could rescind health insurance coverage are

[66] This statement is based on the Departments' conversations with industry experts.
[67] 2009 Current Population Survey.

expected to be affected.[68] 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.[69] This estimate implies there are approximately 10,700 rescissions per year.

c. Benefits

There are many benefits that flow from these interim final regulations, which the Departments believe justify the costs. As noted, Executive Order 12866 requires consideration of "distributive impacts" and "equity." To the extent that rescissions are arbitrary 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. As discussed further in section IV.B.6.b of this preamble, it is also well-documented that lack of insurance leads to lost workplace productivity and additional mortality and morbidity. Thus, these rules would contribute to reducing the burden from lost productivity that arises from people being uncovered. These effects would be especially large relative to the number of individuals affected given that the affected population tends to be much sicker on average.

Specifically, this provision also could protect against interruptions or terminations in care resulting from rescissions. As a result of the statute and these interim final regulations, people with high-cost illnesses at risk of rescission would have continued access to care throughout their illness, possibly avoiding more expensive and debilitating complications down the road. Gaps in

[68] Estimates are from 2007 NAIC financial statements data and the California Department of Managed Healthcare (http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx).
[69] NAIC Rescission Data Call, December 17, 2009, p.1.

health insurance, even if brief, can have significant health and financial consequences.[70] A survey from the Commonwealth Fund found that about three of five adults with any time uninsured said they had not received needed health care in the past year because of costs – more than two times the rate of adults who were insured all year. Further, 44 percent of respondents who had experienced any coverage break during the prior year said they had failed to go to a doctor or clinic when they had a medical problem because of costs, compared with 15 percent of adults who did not experience such breaks.[71]

These interim final regulations will also have substantial financial benefits for individuals who otherwise would have had their policies rescinded. While there has been minimal documentation of financial losses associated with rescissions, reports suggest severe financial hardships may result. In one case, a woman faced more than $129,000 in medical bills and was forced to stop chemotherapy for several months after being dropped by an insurer.[72] The maintenance of coverage through illness not only prevents financial hardship for the particular enrollee, but can also translate into lower premiums for the broader insured population by reducing cost-shifting from the costs of uncompensated care.

d. Costs and Transfers

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, these costs could be partially offset by decreased costs associated with reduced post-claims underwriting under the interim final rule. Due to lack of data on the administrative

[70] This point is discussed further in the section IV.B.6.b. later in this preamble.
[71] Collins et al. "Gaps in Health Insurance: An All American Problem" *Commonwealth Fund* (2006), available http://www.commonwealthfund.org/usr_doc/Collins_gapshltins_920.pdf
[72] 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.

costs of underwriting and post-claims underwriting, as well as lack of data on the full prevalence of rescissions, it is difficult for the Departments to quantify these costs. The new requirement for an advance notice prior to rescission of a policy imposes an hour burden of 350 hours and a cost burden of $29,000. These costs are discussed in more detail in the Paperwork Reduction Act section later in this preamble.

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 relatively sick nature of people who have policies rescinded (who would have difficulty going without treatment), the Departments estimate that these additional costs would be small.

Under this provision of these interim final regulations, 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 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 their increased costs to cover the health care costs of very sick individuals whose policies previously could be rescinded (the precise change in premiums depends on the competitive conditions in specific insurance markets). However, rescissions are extremely rare in group markets where such costs would be most likely to be transferred through premium increases. As described earlier, they are also rare in the individual market, affecting 0.15 percent of policies. In this market, the potential costs would likely be born by the individuals themselves unless they live in a State with regulations limiting rate increases based on health, as discussed further below.

While the Departments are unable to estimate the impact of prohibiting rescissions except in cases of fraud or intentional misrepresentation with certainty, they expect it to be small. Even the high rates of rescission acknowledged by some smaller insurers would still be expected to translate into only a small average impact across the individual health insurance market. And since this small impact across the market would be primarily attributable to insurers paying benefits to persons with substantial medical expenditures, the transfer would be useful.

The Departments assume for their analysis that the individuals covered by the rescinded policies are much sicker than average. Specifically, these individuals are assumed to have total spending in the top 10 percent of spending, which represents about 70 percent of total spending for the population as a whole, as estimated from the 2007 MEPS-HC person level medical expenditure distributions. If the overall NAIC rescission rate of 0.15 percent comes from this subset randomly, then they would account for one percent of claims. Depending on the percentage of rescissions that no longer occur as a result of these interim final regulations, and other changes to the insurance market as detailed below, these claims would now have to be covered, representing a transfer of costs from the affected entities to the larger insured population.

Substantial uncertainty exists around the estimated transfer discussed above. First, since post-claims underwriting is limited by these interim final regulations, plans may expand their pre-claims underwriting practices, potentially leading to increased denials, preexisting condition riders, or rate-ups.[73] This in turn would decrease the number of rescissions, but without expanding coverage or increasing claims paid. Second, there is uncertainty concerning what proportion of the rescissions would be considered to result from fraud or intentional

[73] These interim final regulations eliminate preexisting condition riders for children, but such riders will continue to be allowed for adults until January 1, 2014.

misrepresentation of material fact, and also uncertainty regarding the interaction of this provision with other provisions, such as the elimination of lifetime limits discussed in the impact analysis for PHS Act section 2711, or the prohibition of preexisting condition exclusions for children – since new children will now be able to enroll in policies which also cannot be rescinded. As a result of this uncertainty, the Departments are unable to precisely estimate an overall or average premium impact from this provision, but given the relatively low prevalence of rescissions in the current market, the impact is estimated to be at most a few tenths of a percent.

5. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815-2719AT, 29 CFR 2590.715-2719A, 45 CFR 147.138)

As discussed earlier in this preamble, Section 2719A of the PHS Act and these interim final regulations impose, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of a health care professional and requirements relating to benefits for emergency services. The three requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers. Thus, a plan or issuer that has not negotiated with any provider for the delivery of health care but merely reimburses individuals covered under the plan for their receipt of health care is not subject to the requirements relating to the choice of a health care professional. However, all plans or health insurance coverage are subject to requirements relating to benefits for emergency services. The cost, benefits, and transfers associated with each of these requirements are discussed separately below.

PHS Act section 2719A and these interim final regulations are generally effective for plan years (or, in the case of the individual market, policy years) beginning on or after September 23, 2010.

a. Choice of Health Care Professional

i. Designation of Primary Care Provider

Summary. The statute and these interim 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.

Estimated Number of Affected Entities. Choice or assignment to a primary care provider is typically required by health maintenance organizations (HMOs) and Point of Service plans (POS). Recent data suggest that there are 577 HMOs in the United States,[74] accounting for more than 32.3 million enrollees,[75] of whom about 40 percent have their primary care provider serve as a gatekeeper.[76] Similar data does not exist for POS plans, although as a reference, about 10 percent of workers with ESI are enrolled in POS plans.[77]

PHS Act section 2719A and these interim final regulations only apply 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 these provisions. Moreover, there are no data on the number of plans that auto-assign patients to primary care physicians and do not already allow patients to make the final provider choice, as

[74] Kaiser Family Foundation, "Number of HMOs, July 2008," *available at* http://www.statehealthfacts.kff.org/comparetable.jsp?ind=347&cat=7&sub=85&yr=71&typ=1&sort=a Note that the number of HMOs also includes Medicaid and Medicare only HMOs that are not covered by these interim final regulations.
[75] Departments' estimates are based on the 2009 CPS and the 2008 Medical Expenditure Panel Survey.
[76] *See* Fang, Hai, *et al*., "Has the use of physician gatekeepers declined among HMOs? Evidence from the United States." *International Journal of Health Care Finance and Economics* 9:183–19 5 (2009).
[77] *See* Kaiser Employer Health Benefits Annual Survey, 2009, Exhibit 5.2 ("Distribution of Health Plan Enrollment for Covered Workers, by Firm Size, Region, and Industry, 2009"), *available at* http://ehbs.kff.org/pdf/2009/7936.pdf.

this would be the population to benefit maximally from the interim final rule. 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, as discussed further below.

Benefits. 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.[78] Freedom of choice is an important value, particularly in this domain, even if it cannot easily be turned into monetary equivalents. Provider choice is a strong predictor of patient trust in their provider, which could lead to decreased likelihood of malpractice claims.[79] As well, studies show that better patient-provider trust results in improved medication adherence.[80] Research literature suggests that better patient-provider relationships also increase health promotion and therapeutic effects.[81] Moreover, one study found that adults who identified having a primary care provider, rather than a specialist, as their regular source of care had 33 percent lower annual adjusted health care expenditures and lower adjusted mortality.[82]

Studies have also found that patients who have long-term relationships with their health care providers tend to experience better quality health care. Adults that have a usual provider and place are more likely to receive preventive care and screening services than those who do

[78] *See* Fanjiang, Gary, *et al.*, "Providing Patients Web-based Data to Inform Physician Choice: If You Build It, Will They Come?." *Journal of General Internal Medicine* 22.10 (2007).
[79] Balkrishnan, Rajesh, and Chu-Weininger, Ming Ying L., "Consumer Satisfaction with Primary Care Provider Choice and Associated Trust." *BMC Health Services Research* 22.10 (2007).
[80] 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).
[81] *Ibid. See also* DiMatteo, Robin M., *et al.,* "Physicians' Characteristics Influence Patients' Adherence to Medical Treatment: Results From the Medical Outcomes Study." *Health Psychology* 12.2 (1993), and Bazemore, Andrew, and Phillips, Robert, "Primary Care and Why it Matters for U.S. Health Reform." *Health Affairs* 29.5 (2010).
[82] Franks, P., and K. Fiscella, "Primary Care Physicians and Specialists as Personal Physicians. Health Care Expenditures and Mortality Experience." *Journal of Family Practice* 47 (1998).

not. For example, adults were 2.8 times more likely to receive a flu shot and women between the ages of 20-64 were 3.9 times more likely to receive a clinical breast exam if they had a usual provider and place of service.[83]

Regular contact with primary care providers also can decrease emergency department visits and hospitalizations. One study found that adolescents with the same regular source of care were more likely to receive preventive care and less likely to seek care in an emergency room.[84] Another study found that patients without a relationship with a regular physician were 60 percent more likely to go to the emergency department with a non-urgent condition.[85] Patients that have a usual source of care tend to also have fewer hospital admissions.[86]

Costs and Transfers. Although difficult to estimate given the data limitations described above, the costs for this provision are likely to be minimal. As previously noted, 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.

ii. Designation of Pediatrician as Primary Care Provider

Summary. 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

[83] 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).
[84] Macinko, James, *et al.*, "Contribution of Primary Care to Health Systems and Health." *Milbank Quarterly* 83.3 (2005).
[85] Burstin, "Nonurgent Emergency Department Visits: The Effect of Having a Regular Doctor."
[86] Bazemore, "Primary Care and Why it Matters for U.S. Health Reform."

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 exclusions with respect to coverage of pediatric care.

Estimated Number of Affected Entities. 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 enrollees and plans that would be affected by these provisions. As a reference, there are an estimated 11.8 million individuals under age 19 with ESI who are in an HMO plan.[87]

Benefits. By expanding participating primary care provider options for children to include physicians who specialize in pediatrics, this provision could benefit 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. Considering this research, this provision could lead to better, sustained patient-provider relationships and health outcomes.

In addition, allowing enrollees to select a physician specializing in pediatrics as their children's primary care provider could remove any referral-related delays for individuals in plans that require referrals to pediatricians and do not allow physicians specializing in pediatrics to

[87] U.S. Department of Labor/EBSA calculations using the March 2009 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

serve as primary care providers.[88] The American Academy of Pediatrics (AAP) strongly supports the idea that the choice of primary care clinicians for children should include pediatricians.[89] Relatedly, at least two States have laws providing children immediate access to pediatricians.[90]

Regular pediatric care, including care by physicians specializing in pediatrics, can improve child health outcomes and avert preventable health care costs. For example, one study of Medicaid enrolled children found that when children were up to date for age on their schedule of well-child visits, they were less likely to have an avoidable hospitalization at a later time.[91] Likewise, if providers are able to proactively identify and monitor obesity in child patients, they may reduce the incidence of adult health conditions that can be expensive to treat; various studies have documented links between childhood obesity and diabetes, hypertension, and adult obesity.[92] One recent study modeled that a one-percentage-point reduction in obesity among twelve-year-olds would save $260.4 million in total medical expenditures.[93]

Giving enrollees in covered plans (that require the designation of a primary care provider) the ability to select a participating physician who specializes in pediatrics as the child's primary care provider benefits individuals who would not otherwise have been given these choices. Again, the extent of these benefits will depend on the number of enrollees with children

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[88] There is no data available to estimate the number of plans that fall into this category.
[89] *See* AAP Policy, "Guiding Principles for Managed Care Arrangements for the Health Care of Newborns, Infants, Children, Adolescents, and Young Adults," *available at* http://aappolicy.aappublications.org/cgi/reprint/pediatrics;105/1/132.pdf.
[90] For example, Michigan and North Carolina mandate direct access to pediatricians as a part of patients' rights requirements. *See* Kaiser Family Foundation, "Patients' Rights: Direct Access to Providers, 2008," *available at* http://www.statehealthfacts.kff.org/comparetable.jsp?ind=364&cat=7.
[91] Bye, "Effectiveness of Compliance with Pediatric Preventative Care Guidelines Among Medicaid Beneficiaries."
[92] "Working Group Report on Future Research Directions in Childhood Obesity Prevention and Treatment." National Heart Lung and Blood Institute, National Institute of Health, U.S. Department of Health and Human Services (2007), *available at* http://www.nhlbi.nih.gov/meetings/workshops/child-obesity/index.htm.
[93] *Ibid*.

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.

Costs and Transfers. Although difficult to estimate given the data limitations described above, 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 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 these interim 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.[94]

iii. Patient Access to Obstetrical and Gynecological Care

Summary. The statute and these interim 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. These plans and issuers must also treat the provision of obstetrical and gynecological care, and the ordering of

[94] http://www.merritthawkins.com/pdf/2008-mha-survey-primary-care.pdf

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.

Estimated Number of Affected Entities. Requiring referrals or authorizations to health care professional who specializes in obstetrics or gynecology (OB/GYNs) is typically required by health maintenance organizations (HMOs) and Point of Service plans (POS). As a reference, according to the 2004 Kaiser Women's Health Survey, 46 percent of women reported seeing an OB/GYN in the past year and 47 percent of women of reproductive age counted OB/GYNs among their routine health care providers.[95] In 2006, there were 69.4 million visits to an OB/GYN according to the National Ambulatory Medical Care Survey conducted by the Centers for Disease Control and Prevention.[96] Although more recent data is not available, a 1999 survey showed that 60 percent of all OB/GYNs in plans requiring the designation of a primary care provider reported that their gynecologic patients were either limited or barred from seeing their OB/GYNs without first getting permission from another physician, and 28 percent reported that their pregnant patients needed permission before seeing an OB/GYN.[97] Nearly 75 percent of surveyed OB/GYNs reported that their patients needed to return to their primary care physicians for permission before they could provide necessary follow-up care.

Notably, beginning in 1994, due to both consumer demand and efforts to regulate managed care, many States passed direct access laws for OB/GYNs, allowing patients to seek

[95] *See* Salganicoff, Alina, *et al.,* "Women and Health Care: A National Profile." Kaiser Family Foundation (2005).
[96] *See* Cherry, Donald K., *et al*., "National Ambulatory Medical Care Survey: 2006 Summary." National Health Statistics Reports (August 2008), Centers for Disease Control and Prevention, *available at* http://www.cdc.gov/nchs/data/nhsr/nhsr003.pdf.
[97] *See* American College of Obstetricians and Gynecologists/Princeton Survey Research Associates, 1999.

care at an OB/GYN office without a referral from a primary care physician. As of 2008, 36 States plus the District of Columbia have laws that provide direct access to OB/GYNs. However, 14 States have not mandated direct access: Alaska, Arizona, Hawaii, Indiana, Iowa, Nebraska, New Jersey, New Mexico, North Dakota, Oklahoma, South Dakota, Tennessee, Vermont, and Wyoming.[98] This provision gives females direct access to OB/GYNs in covered plans in these States, who may otherwise not have had this direct access. As well, because State law is preempted by ERISA, women in self-insured plans did not previously receive this legal protection. In addition, these women will not need to get an authorization from their primary care provider for the care and ordering of obstetrical and gynecological items and services by their participating OB/GYN.

These interim final regulations apply 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. As a reference, there are an estimated 14.8 million females between ages 21 to 65 with ESI who are in HMO plans.[99]

Benefits. 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 get an authorization from a primary care provider to provide care and order obstetrical and gynecological items and services. To the extent that

[98] Kaiser Family Foundation, "Mandates Direct Access to OB/GYNs?," *available at* http://www.statehealthfacts.kff.org/comparemaptable.jsp?ind=493&cat=10&sub=114

[99] U.S. Department of Labor/EBSA calculations using the March 2009 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

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 could improve the treatment and health outcomes of female patients.

Access to such care can have substantial benefits in women's lives. About 42,000 American women die each year from breast cancer, and it is estimated that about 4,000 additional lives would be saved each year just by increasing the percentage of women who receive recommended breast cancer screenings to 90 percent.[100] As well, regular screening with pap smears is the major reason for the 30-year decline in cervical cancer mortality.[101]

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.

Costs and Transfers. 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.

[100] *See* National Commission on Prevention Priorities, "Preventive Care: A National Profile on Use, Disparities, and Health Benefits." Partnership for Prevention, August 2007.
[101] *See* "Preventive Care: A National Profile on Use, Disparities, and Health Benefits" at 26.

To the extent these interim final regulations result in a shift in services to higher cost providers, it would 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.

b. Coverage of Emergency Services

i. Summary

PHS Act section 2719A and these interim 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, these interim 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. These interim final regulations also provide that a plan or health insurance issuer pay for out-of-network emergency services (prior to imposing in-network cost-sharing), the greatest of: (1) the median in-network rate; (2) the usual customary and reasonable rate (or similar rate determined using the plans or issuer's general formula for determining payments for out-of-network services); or (3) the Medicare rate.

In applying the rules relating to emergency services, the statute and these interim final 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. There are, however, some variances from the EMTALA definitions.

The statute and these interim final 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.

ii. Estimated Number of Affected Entities

These interim final regulations will directly affect out-of-pocket expenditures for individuals enrolled in non-grandfathered private health insurance plans (group or individual) whose copayment or coinsurance arrangements for emergency services differ between in network and out of network providers. These interim final regulations may also require some health plans to make higher payments to out of network providers than are made under their current 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.

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 currently exist in the marketplace. Many of the large insurers maintained identical copayment and/or coinsurance arrangements between in and out of network providers. Others have 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.

Although these data do not permit quantitative estimates of plans or persons affected, other data can be illustrative of overall magnitudes for emergency services. For a point of reference, in 2005, 115.3 million visits were made to hospital emergency departments. Of these, 39.9 percent were made by individuals with private insurance. This represents approximately 46.0 million visits, at approximately 1.7 visits per insured person that utilized emergency department services, or 27.4 million people.[102] While data on rates of out-of-network emergency room encounters is sparse, the Blue Cross Blue Shield (BCBS) Association reports that nationally about 8 percent of its emergency room visits are sought out-of-network.[103] Given the breadth of the Blue Cross networks, it is reasonable to assume that 8 percent to 16 percent of emergency room visits are out-of-network each year, since a plan with a smaller provider network will be more likely to have out-of-network use by enrollees. If each individual was equally likely to utilize out of network services, a maximum of 2.1 to 4.2 million individuals would be potentially affected by differing out-of-pocket requirements. Based on the informal survey, some proportion, possibly a large portion, of these individuals are covered by plans that have identical in and out-of-network requirements. Therefore, the number of individuals affected by this regulatory provision would be smaller.

iii. Benefits

Insurers maintain differing copayment and coinsurance arrangements between in- and out-of-network providers as a cost containment mechanism. Implementing reduced cost sharing

[102] Vital and Health Statistics, Advanced Data No. 386, June 29, 2007

[103] BCBS, however, reports its rates vary considerably by State, with 11 States having double digit rates ranging from 10 percent to a high of 41 percent. Moreover, because BCBS has reciprocity between many State Blue Cross Blue Shield plans, its statistics for out of network emergency services utilization should be considered a conservative estimate of the proportion of ER services that insured individuals receive out-of-network.

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. These interim final regulations eliminate this disparity in out-of-pocket burden for enrollees, leading to potentially substantial financial benefit.

These interim final 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 could 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.

iv. Costs and Transfers

The economic costs associated with the emergency department provisions are likely to be minimal. These costs would occur to the extent that any lower cost-sharing would 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.

The emergency services provisions are likely to result in some transfers from the general membership of non-grandfathered group policies that have differing copayment and coinsurance arrangements to those policy holders that use the out-of-network emergency services. The transfers could occur through two avenues. First, if there is reduced cost sharing for out-of-network emergency services, then plans must pay more when enrollees use those services. Out-of-pocket costs for the enrollees using out-of-network services will decrease, while plan costs will get spread across the insured market. Second, if the provision results in plans paying higher rates than they currently do for out-of-network providers, then those costs will get spread across the insured market while the individual enrollees using out-of-network care would potentially get a smaller balance bill. For all of the data issues described above, the precise amount of the transfer which would occur through an increase in premiums for these group plans is impossible to quantify with any precision, but it is likely to be less than one-tenth of one percent of premium, and only applies to non-grandfathered health plans.

c. Application to Grandfathered Health Plans

As discussed earlier in this preamble, the statute and these interim final regulations 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**.**

d. 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, these interim 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 interim 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 estimate that the cost to plans and insurance issuers to prepare and distribute the disclosure is $6.1 million in 2011. For a discussion of the Patient Protection Disclosure Requirement, see the Paperwork Reduction Act section later in this preamble.

6. Combined Effects of the Insurance Market Reforms

a. Summary

The Affordable Care Act includes a number of provisions that are effective for plan years (or in the case of individual health insurance coverage, for policy years) beginning on or after September 23, 2010. These interim final regulations include four of those provisions whose purpose is to improve consumer protections. Two additional provisions – the extension of dependent coverage to adult children and the rules defining a grandfathered health plan – were

the subject of previously published interim final regulations. The implementation of other provisions – including those relating to coverage of preventive services (PHS Act section 2713) and appeals (PHS Act section 2719) – will be addressed in future regulations.

This set of regulations is distinct from the others in that its primary beneficiaries are people who generally already have some type of illness, injury or disability. The provision prohibiting preexisting condition exclusions for children could help 31,000 to 72,000 uninsured children gain insurance, and up to 90,000 children who have insurance with benefit carve-outs or preexisting condition exclusion periods. The policy on restricted annual limits could help up to 2,700 to 3,500 people who hit these limits each year; the prohibition on lifetime limits could help 18,650 to 20,400 each year who would be expected to have costs that exceed a limit. Based on an NAIC survey, the Departments estimate there are approximately 10,700 rescissions of policies in the individual market each year, and these interim final regulations are expected to reduce this number substantially.[104] And one of the patient protections, access to emergency care from out-of-network providers, could limit the out-of-pocket spending for up to 2.1 to 4.2 million individuals with some acute health care need. While the estimates on the number of people affected by these policies may be relatively small, a much larger number of Americans are at risk of hitting one of these barriers to insurance coverage and will gain indirect benefits of the legislation. This section describes the potential combined benefits, costs, and transfers of these provisions.

b. Benefits

These interim final regulations could generate significant economic and social welfare benefits to consumers. This would take the form of reductions in mortality and morbidity, a reduction in medical expenditure risk, an increase in worker productivity, and a decrease the

[104] NAIC Rescission Data Call, December 17, 2009, p.1.

cross-subsidy in premiums to offset uncompensated care, sometimes referred to as the "hidden tax." Each of these effects is described below. It should be noted that the benefits described are substantially greater in each of these areas once all the protections of the full Affordable Care Act are effective.

A first type of benefit is reductions in mortality and morbidity. While the empirical literature leaves many questions unresolved, a growing body of evidence convincingly demonstrates that health can be improved by spending more on at-risk individuals and by expanding health insurance coverage. For example, Almond et al.[105] find that newborns classified just below a medical threshold for "very low birthweight" have *lower* mortality rates than newborns classified as just above the threshold, despite an association between low birth weight and higher mortality in general, because they tend to receive additional medical care. In a study of severe automobile accidents, Doyle[106] found that uninsured individuals receive less care and have a substantially higher mortality rate. Currie and Gruber[107] found that increased eligibility for Medicaid coverage expanded utilization of care for otherwise uninsured children, leading to a sizeable and significant reduction in child mortality. A study of Medicare by Card et al.[108] found that individuals just old enough to qualify for coverage have lower mortality rates – despite similar illness severity – than do those just too young for eligibility. Finally, a report by

[105] Almond, Douglas, Joseph J. Doyle, Jr., Amanda E. Kowalski, and Heidi Williams. "Estimating Marginal Returns to Medical Care: Evidence from At-Risk Newborns." The Quarterly Journal of Economics, May 2010, 125(2): 591-634. http://www.mit.edu/~jjdoyle/vlbw.pdf.
[106] Doyle, Joseph J. "Health Insurance, Treatment and Outcomes: Using Auto Accidents as Health Shocks." The Review of Economics and Statistics, May 2005. 87(2):256-270. http://www.mitpressjournals.org/doi/abs/10.1162/0034653053970348.
[107] Currie, Janet and J. Gruber. "Health Insurance Eligibility, Utilization of Medical Care, and Child Health." The Quarterly Journal of Economics, May 1996. 111(2):431-466. http://www.jstor.org/stable/2946684?cookieSet=1.
[108] Card, David, C. Dobkin, and N. Maestas. "Does Medicare Save Lives?" The Quarterly Journal of Economics, May 2009. 124(2):597-636. http://www.mitpressjournals.org/doi/abs/10.1162/qjec.2009.124.2.597.

the Institute of Medicine (IOM)[109] found mortality risks for uninsured individuals that were 25 percent higher than those of observably similar insured individuals. In addition to the prospect that expanded insurance coverage will result in reductions in mortality, it will almost certainly substantially reduce morbidity, as demonstrated in extensive reviews of the literature by Hadley and the IOM.[110]

These interim final regulations will expand access to currently uninsured individuals. These newly insured populations will likely achieve both mortality and meaningful morbidity reductions from the regulations, especially those populations who face rescissions, restricted annual or lifetime limits, or preexisting conditions exclusions, since they are on average in worse health and thus likely to benefit even more from insurance coverage than uninsured individuals in general.

Because considerable uncertainty surrounds any specific estimate of the effect of expanded coverage on mortality and morbidity, this benefit is not quantified in this analysis.[111] However, the Departments conclude that reductions in mortality and morbidity are likely to be a significant benefit of these interim final regulations and will become substantially greater in 2014 and subsequent years, when millions of additional individuals will obtain health insurance coverage.

A second type of benefit from the cumulative effects of these interim final regulations is a reduction in medical risk. A central goal of health insurance is to protect individuals against catastrophic financial hardship that would come with a debilitating medical condition. By

[109] Institute of Medicine. *Care Without Coverage: Too Little, Too Late.* Washington, DC: National Academy Press, 2002. http://books.nap.edu/openbook.php?record_id=10367&page=R1.
[110] Institute of Medicine, op. cit. Hadley J. Sicker and Poorer: The consequences of being uninsured. Medical Care Research and Review, Vol. 60, No. 2 suppl, 3S-75S (2003)
[111] Kronick, Richard. "Health insurance coverage and mortality revisited." Health Services Research. April 2009. 44(4):1211-1231. http://www3.interscience.wiley.com/journal/122342601/abstract?CRETRY=1&SRETRY=0.

pooling expenses across healthy and sick individuals, insurance can substantially improve the economic well-being of the sick while imposing modest costs on the healthy. This insurance is valuable, and economic theory suggests that the gains to the sick from a properly implemented insurance system far exceed the costs to healthy individuals. A recent paper shows that the benefits from this reduction in exposure to financial risks would be sufficient to cover almost two-fifths of insurance costs.[112] Previous research also suggests that protecting patients who have very high medical costs or low financial assets is likely to have even larger benefits. Indeed, research indicates that approximately half of the more than 500,000 personal bankruptcies in the U.S. in 2007 were to some extent contributed to by very high medical expenses.[113] Exclusions from health insurance coverage based on preexisting conditions expose the uninsured to the aforementioned financial risks. Rescissions of coverage and binding annual or lifetime limits on benefits increase the chance that medical expenditures will go uncompensated, exposing individuals to the financial risks associated with illness. Regulations that prevent these practices thus reduce the uncertainty and hardship associated with these financial risks. Moreover, because they secure coverage for individuals with high probabilities of incurring extensive medical expenses, regulations that guard against rescissions and prevent insurance exclusion based on preexisting conditions for children are likely to have especially large economic benefits in terms of reducing financial risk. These interim final regulations will help insurance more effectively protect patients from the financial hardship of illness, including bankruptcy and reduced funds for non-medical purposes.

A third type of benefit from these interim final regulations is improved workplace productivity. These interim final regulations will benefit employers and workers by increasing

[112] Amy Finkelstein and Robin McKnight. What Did Medicare Do? The Initial Impact of Medicare on Mortality and Out of Pocket Medical Spending. 2008. *Journal of Public Economics* 92: 1644-1669.
[113] David Himmelstein et al, 2009.

workplace productivity and reducing absenteeism, low productivity at work due to preventable illness, and "job-lock." A June 2009 report by the Council of Economic Advisers found that increased access to health insurance coverage improves labor market outcomes by improving worker health.[114] The health benefits of eliminating coverage rescissions and lifetime coverage limits, restricting annual limits, and expanding access to primary care providers and OB/GYNs will help to reduce disability, low productivity at work due to preventable illness, and absenteeism in the work place, thereby increasing workplace productivity and labor supply. Economic theory suggests that these benefits would likely be shared by workers, employers, and consumers. In addition, these interim final regulations will increase labor market efficiency by reducing "job lock," or the reluctance to switch jobs or engage in entrepreneurship because such activities would result in the loss of health insurance or limitations on coverage. For example, without the regulations, a parent with generous coverage for a child with a medical condition might fear moving to a different employer or launching his or her own business given the concern that the new plan could exclude coverage for the child on the basis of the preexisting condition. These reforms will increase not only productivity and innovation through entrepreneurship, but also worker wages since job lock prevents workers from pursuing jobs with potentially higher salaries.[115] The Council of Economic Advisers' June 2009 report estimates that for workers between the ages of 25 and 54, the short-term gain from eliminating job lock would be an increase in wages of 0.3 percent.

Fourth, the Affordable Care Act's provisions will reduce the transfers in the health care system due to cost shifting of uncompensated care that lead to higher premiums for private insurance. The insurance market regulations will help expand the number of individuals who are

[114] Council of Economic Advisers. "The Economic Case for Health Reform." (2009).
[115] Gruber, J. and B. Madrian. "Health Insurance, Labor Supply, and Job Mobility: A Critical Review of the Literature." (2001).

insured and reduce the likelihood that individuals who have insurance do not bankrupt themselves by paying medical bills. Both effects will help reduce the amount of uncompensated care that imposes a "hidden tax" on consumers of health care since the costs of this care are shifted to those who are able to pay for services in the form of higher prices.

The Departments provide here an order of magnitude for the compensatory reduction in cost-shifting of uncompensated care that is associated with the expansion of coverage of these interim final regulations**.** Three assumptions were made. First, the uninsured populations affected by these interim final regulations tend to have worse health, greater needs for health care, higher health care spending, and less ability to reduce utilization when they are uninsured. These interim final regulations are therefore unlikely to induce as much demand for health care as would be assumed for the uninsured population in general when coverage expands. As such, the Departments assume that extending insurance coverage to this group is unlikely to significantly increase the overall costs of the U.S. health care system. The Departments therefore assume that the vast majority of the premium increases estimated in this regulatory impact analysis result from transfers from out-of-pocket or uncompensated care costs to covered costs, although we emphasize that there is considerable uncertainty surrounding this estimate.

Second, on the basis of the economics literature on the subject,[116] the Departments estimate that two-thirds of the previously uncovered costs would have been uncompensated care (with the remaining one-third paid for out-of-pocket), of which 75 percent would have been paid for by public sources, and 25 percent would have been paid for by private sources. If reductions in privately-financed uncompensated care are passed on in the form of lower prices charged by hospitals, and result in lower insurance premiums charged to consumers, then the Departments

[116] Hadley, Jack, J. Holahan, T. Coughlin, and D. Miller. "Covering the Uninsured in 2008: Current Costs, Sources of Payment, and Incremental Costs." Health Affairs, 2008, 27(5): w399¬w415.

estimate that increased insurance coverage for the vulnerable populations affected by these interim final regulations could result in reductions in insurance premiums of up to $1 billion in 2013.[117] There would also be corresponding decreases in public expenditure as uncompensated care is reduced.

c. Costs and Transfers

Premiums reflect both effects on health system costs as well as transfers in the payment of costs from one payer or group of individuals to another. For example, as consumer protections expand coverage and/or reduce cost-sharing, the costs for services that people previously paid for out of pocket – often creating substantial burdens as described above – will be distributed over a wider insured population. On the other hand, the cost-shifting that previously occurred onto the insured population when people could no longer pay for their out-of-pocket care will be reduced. Expansion of coverage will also generate induced demand for services, with corresponding benefits to health and productivity. These costs and transfers together will generate a change in premiums. As discussed previously, the populations affected by these interim final regulations tend to be in poorer health than the general uninsured population, leading to less induced demand when coverage expands.

The Departments estimate that the premium effect of prohibiting preexisting condition exclusions for children would be on average one percent or less in the individual market and negligible in the group market. The provisions relating to annual and lifetime limits would have

[117] The Departments come to this estimate using the following methods. First, they estimated the proportion of the population in group and individual markets using the Medical Expenditure Panel Survey (2008). Next, information from 75 FR 34538 (June 17,2010) was used to estimate the proportion of employer and individual plans that maintain or lose grandfather status by 2013. Projections of national health expenditures from the National Health Expenditure Accounts to 2013 were distributed among these groups, and premium impacts as discussed in this regulatory impact analysis were applied. Potential premium reductions secondary to reductions in the cost-shifting of uncompensated care were then calculated using the information from the economic literature as presented in this discussion. The Departments note that to the extent that not all of the reductions in uncompensated care costs are passed onto insured populations, these estimates may be an overestimate.

approximately one-half of one percent impact on premiums in the group market and less than a one percent impact on premiums in the individual market. While the prohibition on lifetime limits applies to individual plans that are grandfathered, the restricted annual limit policy and preexisting condition exclusion policy for children do not, limiting the premium effect for the grandfathered market. Although precise estimates of the effects of restricting rescissions and expanding patient protections are even more difficult to make than for preexisting condition exclusions or annual and lifetime limits, the Departments' analysis suggest that the effects of restricting rescissions will be no more than a few tenths of one percent of premium, and that patient protections will increase premiums by less than one tenth of one percent.

The Departments emphasize that these individual premium effects cannot be simply added to get a combined impact on premiums for several reasons. The first relates to their simultaneous implementation. Quantifying the precise and unique premium impact of policies that take effect at the same time is difficult. Health insurers will consider the totality of the provisions in making decisions about coverage modifications, so that disentangling the effects of each provision is impossible. This is especially so given the complex interactions among the policies. For example, prohibiting rescissions and lifetime limits could mean that someone who would have had a policy rescinded now maintains coverage, and also maintains coverage beyond a previous lifetime limit. Under the current guaranteed renewability protections in the individual market, if a child with a preexisting condition is now able to obtain coverage on a parental plan, he or she can potentially stay on that plan until age 26.

This difficulty is compounded by the flexibility afforded in the grandfather rule. Plans and issuers will consider the cumulative impact of these provisions when making decisions about whether or not to make other changes to their coverage that could affect their grandfather status.

It can be expected that the plans that are most affected by these provisions in terms of potential premium impact will likely be the most aggressive in taking steps to maintain grandfather status, although, as described in that regulatory impact analysis, other factors affect plans' decisions as well. It is unlikely that plans will make this calculation multiple times for the multiple provisions that will take effect at the same time.

Lastly, estimating these effects cumulatively compounds the errors of highly uncertain estimates. As discussed, plan and enrollee behaviors may change in response to the incentives created by these interim final regulations. Data are also limited in many areas, including: the prevalence of annual limits in insurance markets; characteristics of high-cost enrollees; prevalence and characteristics of rescissions; and take-up rates under different insurance scenarios. As discussed above, the estimates presented here, by necessity, utilize "average" experiences and "average" plans. Variability around the average increases substantially when multiple provisions are considered, since the number of provisions that affect each plan will differ (for example, a plan may already offer coverage without preexisting condition exclusions and bar rescissions, meaning they will not be affected by those provisions, but may have a lifetime limit of $1 million, meaning they will be affected by that provision). Different plans also have different characteristics of enrollees, for example in terms of age or health status, meaning that provisions such as eliminating lifetime limits could affect them differently. It is especially important to note the variation in insurance market reforms across States. Only a few States have community rating, where costs get distributed across the entire insured pool. Fractions of the cost will get distributed across the pool and to individual enrollees in other States depending on the degree of rating restrictions, if any exist. Uncertainty compounds as ranges and errors and assumptions are summed across provisions.

D. Regulatory Flexibility Act--Department of Labor and Department of Health and Human Services

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 APA (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B or title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

Moreover, under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA, because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. Consistent with the policy of the RFA, the Departments encourage the public to submit comments that suggest alternative rules that accomplish the stated purpose of the Affordable Care Act and minimize the impact on small entities.

E. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these interim final regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

F. Paperwork Reduction Act

1. Department of Labor and Department of Treasury

As further discussed below, these interim final regulations contain enrollment opportunity, rescission notice, and patient protection disclosure requirements that are information collection requests (ICRs) subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). Each of these requirements is discussed in detail below.

Currently, the Departments are soliciting 60 days of public comments concerning these disclosures. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395-7285 or by email to oira_submission@omb.eop.gov. A copy of the ICR may be obtained by contacting the 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. E-mail: ebsa.opr@dol.gov. ICRs submitted to OMB also are available at reginfo.gov (http://www.reginfo.gov/public/do/ PRAMain).

a. ICR Regarding Affordable Care Act Enrollment Opportunity Notice Relating to Lifetime Limits

As discussed earlier in this preamble these interim final regulations require a plan or issuer to provide an individual whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits with an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (or, in the individual market, policy year) beginning on or after September 23, 2010 (which

is the applicability date of PHS Act section 2711). Coverage must begin not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.[118] The Affordable Care Act dependent coverage enrollment notice is an ICR subject to the PRA.

The Departments estimate that approximately 29,000 individuals qualify for this enrollment right, which as discussed more fully below, should be considered an upward bound. The estimate is based on the following methodology. The Departments estimate that of the approximately 139.6 million individuals in ERISA-covered plans,[119] 63 percent of such individuals are covered by plans with lifetime limits.[120]

While limited data are available regarding lifetime limits, the Departments estimated that the average lifetime limit across all markets is about $4.7 million,[121] which means that an individual would exceed a lifetime limit by incurring at least $4.7 million in medical expenses during one year or across many years. Although the Departments are unable to track spending across time to estimate the number of individuals that would reach the lifetime limit, the Departments estimate that about 0.033 percent of individuals incur more than $1 million in medical spending in a year.[122] If these individuals incurred this amount every year, 29,000 individuals would incur expenses of at least $4.7 million limit by the fifth year.

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[118] The interim final regulations require any individual enrolling in group health plan coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under HIPAA portability rules. Accordingly, the individual must be offered all the benefit packages available to similarly situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage due to reaching a lifetime limit

[119] The Departments' estimate is based on the 2009 March Current Population Survey (CPS).

[120] The Departments' estimate for large and small employer health plans is derived from The Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), *at* http://ehbs.kff.org/pdf/2009/7936.pdf, Exhibit 13.12.

[121] The Departments' estimate is based on America's Health Insurance Plans, *Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits*, (Oct. 2009) *at* http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf, Table 17; and America's Health Insurance Plans, *Individual Health Insurance 2008: Small Group Health Insurance* , Table 22.

[122] The Departments' estimate is based on adjusted insurer claims and MEPS-HC expenditures.

There are several reasons to suspect that these assumptions lead to an over-estimate. First, individuals would have to average $1 million in medical expenses per year to exceed the $4.7 million limit. Second, an individual's lifetime limit is reset if he switches employers or, for employees who work for employers with multiple health insurance coverage options, switches to a different health insurance plan.

The interim final regulations require plans or insurers to notify individuals whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits that they are now eligible to reenroll in the plan or policy. The Departments assume that the notice for all plans and policies (including self-insured plans that are administered by insurers) will be prepared by the estimated 630 health insurers operating in the United States.[123] On average, the Departments expect that one-half hour of a legal professional's time, valued as $119, will be required to draft this notice, resulting in an hour burden of approximately 160 hours with an equivalent cost of $19,000.

The Departments assume that insurers track information regarding individuals that have lost coverage due to reaching a lifetime limit (including contact information in their administrative records). Based on the foregoing, the Departments estimate that, on average, five minutes of a clerical staff member's time, valued at $26 per hour will be required to incorporate the specific information into the notice and mail the estimated 29,000 notices. This results in an estimated hour burden of approximately 2,400 hours with an equivalent cost of $63,000.

[123] While plans could prepare their own notice, the Departments assume that the notices will be prepared by service providers. The Departments have previously estimated that there are 630 health insurers (460 providing coverage in the group market, and 490 providing coverage in the individual market.). These estimates are from NAIC 2007 financial statements data and the California Department of Managed Healthcare (2009), *at http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx*. Because the hour and cost burden is shared between the Departments of Labor/Treasury and the Department of Health and Human Services, the burden to prepare the notices is calculated using half the number of insurers (315).

Therefore, the total hour burden of this notice requirement is approximately 2,600 hours with an equivalent cost of $82,000.

The associated cost burden of the rule results from material and mailing costs that are required to distribute the estimated 29,000 notices. The Departments estimate that the notice will be one-page in length, material and print costs will be five cents per page, and postage will be 44 cents per notice resulting in a per notice cost of 49 cents. This leads to a total cost burden of approximately $14,000 to distribute the notices.

Type of Review: New collection.

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

Title: Notice of Special Enrollment Opportunity under the Patient Protection and Affordable Care Act Relating to Lifetime Limits.

OMB Number: 1210–0143; 1545–2179.

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

Total Respondents: 315.

Total Responses: 29,000.

Frequency of Response: One-time.

Estimated Total Annual Burden Hours: 1,300 hours (Employee Benefits Security Administration); 1,300 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: $7,000 (Employee Benefits Security Administration); $7,000 (Internal Revenue Service).

b. ICR Regarding Affordable Care Act Notice Relating to Rescission

As discussed earlier in this preamble, PHS Act Section 2712 and these interim 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 interim 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.

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 group health plan policies are rescinded in a year. The Departments estimate that there is an average of 16 participants in small, insured plans.[124] Based on these numbers the Departments estimate that approximately 100 policies are rescinded during a year, which would result in 1,600 notices being sent to affected participants. The Departments estimate that 15 minutes of legal profession time at $119 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 $26 per hour would be required to distribute the notice. This results in an hour burden of approximately 50 hours with an equivalent cost of approximately $3,700. The Departments estimate that the cost burden associated with distributing the notices will be approximately $800.[125]

These paperwork burden estimates are summarized as follows:

[124] U.S. Department of Labor, EBSA calculations using the March 2008 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

[125] This estimate is based on an average document size of one page, $.05 cents per page material and printing costs, and $.44 cent postage costs.

Type of Review: New 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: 1,600.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 25 hours (Employee Benefits Security Administration); 25 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: $400 (Employee Benefits Security Administration); $400 (Internal Revenue Service).

c. ICR Regarding Affordable Care Act Patient Protection Disclosure Requirement

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 a 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; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, these interim 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 interim 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 interim final regulations' patient protection disclosure requirement, the Departments estimate that 339,000 ERISA-covered plans will need to notify an estimated 8.0 million policy holders of their plans' policy in regards to designating a primary care physician and for obstetrical or gynecological visits.[126] The following estimates are based on the assumption that 22 percent of group health plans will not have grandfathered health plan status in 2011. Because the interim final regulations provide model language for this purpose, the Departments estimate that five minutes of clerical time (with a labor rate of $26.14/hour) will be required to incorporate the required language into the plan document and ten minutes of an human resource professional's time (with a labor rate of $89.12/hour) will be required to review the modified language. [127] Therefore, the Departments estimate that plans will incur a one-time hour burden of 85,000 hours with an equivalent cost of $5.8 million to meet the disclosure requirement in the first year.

[126] The Departments' estimate of the number of ERISA-covered health plans was obtained from the 2008 Medical Expenditure Panel Survey's Insurance component. The estimate of the number of policy holders was obtained from the 2009 Current Population Survey. Information on HMO and POS plans and enrollment in such plans was obtained from the Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2009. The methodology used to estimate the percentage of plans that will not be grandfathered in 2011 is addressed in the Departments' Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act that were issued on June 17, 2010 (75 FR 34538).
[127] EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the interim 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. This results in a cost burden of $124,000 ($0.05 per page*1/2 pages per notice * 8.0 million notices*0.62).

Plans that relinquish their grandfather status in subsequent years also will become subject to this notice requirement and incur a cost to prepare and distribute the notice in the year they relinquish their grandfather status. The Departments estimate a total hour burden of 62,000 hours in 2012 and 50,000 in 2013 for plans relinquishing their grandfather status in 2012 or 2013. There also will be an estimated total cost burden of $90,000 in 2012 and $73,000 in 2013.

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: New 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 262,000 (three year average).

Total Responses: 6,186,000 (three year average).

Frequency of Response: One time

Estimated Total Annual Burden Hours: 33,000 (Employee Benefits Security Administration); 33,000 (Internal Revenue Service).

Estimated Total Annual Burden Cost: $48,000 (Employee Benefits Security Administration); $48,000 (Internal Revenue Service).

2. Department of Health and Human Services

As discussed above in the Department of Labor and Department of the Treasury PRA section, these interim final regulations contain an enrollment opportunity notice, rescissions notice, and patient protection disclosures requirement for issuers. These requirements are information collection requirements under the Paperwork Reduction Act. Each of these requirements is discussed in detail below.

a. ICR Regarding Affordable Care Act Enrollment Opportunity Notice Regarding Lifetime Limits

PHS Act section 2711 and these interim final regulations requires health insurance issuers offering individual health insurance coverage to provide an individual whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits with an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (or, in the individual market, policy year) beginning on or after September 23, 2010 (which is the applicability date of PHS Act section 2711).

Coverage must begin not later than the first day of the first plan year (or policy year in the individual market) beginning on or after September 23, 2010.[128]

The Department estimates that approximately 13,182 individuals qualify for this enrollment right, which as discussed more fully below, should be considered an upward bound. The estimate is based on the following methodology. The Department estimates that of the approximately 16.5 million individuals[129] covered by family policies in the individual market, 89 percent of such individuals have a policy with a lifetime limit.[130] The Department also estimates that out of the approximately 40.1 million individuals covered by public, non-Federal employer group health plans sponsored by State and local governments,[131] 63 percent of such individuals are covered by plans with lifetime limits.[132]

While limited data are available regarding lifetime limits, the Department estimated that the average lifetime limit across all markets is about $4.7 million,[133] which means that an individual would exceed a lifetime limit by incurring at least $4.7 million in medical expenses during one year or across many years. Although the Department is unable to track spending across time to estimate the number of individuals that would reach the lifetime limit, the Department estimates that about 0.033 percent of individuals incur more than $1 million in

[128] The interim final regulations require any individual enrolling in group health plan coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under HIPAA portability rules. Accordingly, the individual must be offered all the benefit packages available to similarly situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage due to reaching a lifetime limit

[129] The Department's estimate is based on the 2009 March Current Population Survey (CPS).

[130] The Department's estimate for individual health plans is derived from America's Health Insurance Plans, *Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits*, (Oct. 2009) *at http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf*, Table 10 and Table 17.

[131] The Department's estimate is based on the 2009 March Current Population Survey (CPS).

[132] The Departments' estimate for large and small employer health plans is derived from The Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), *at http://ehbs.kff.org/pdf/2009/7936.pdf*, Exhibit 13.12.

[133] The Department's estimate is based on America's Health Insurance Plans, *Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits*, (Oct. 2009) *at http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf*, Table 17; and America's Health Insurance Plans, *Individual Health Insurance 2008: Small Group Health Insurance* , Table 22.

medical spending in a year.[134] If these individuals incurred this amount every year, 13,000 individuals would incur expenses of at least $4.7 million limit by the fifth year.

There are several reasons to suspect that these assumptions lead to an over-estimate. First, individuals who incur $1 million of medical expenses in a year would need to sustain this level every year for five years to exceed the $4.7 million limit. Second, an individual's lifetime limit is reset if he switches employers or, for employees who work for employers with multiple health insurance coverage options, switches to a different health insurance plan.

These interim final regulations require plans or insurers to notify individuals whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits that they are now eligible to reenroll in the plan or policy. The Department assumes that the notice for all plans and policies (including self-insured plans that are administered by insurers) will be prepared by the estimated 630 health insurers operating in the United States.[135] On average, the Department expects that one-half hour of a legal professional's time, valued as $119, will be required to draft this notice, resulting in an hour burden of approximately 200 hours with an equivalent cost of $19,000.

The Department assumes that plans and insurers track information regarding individuals that have lost coverage due to reaching a lifetime limit (including contact information) in their administrative records. Based on the foregoing, the Department estimates that, on average, five minutes of a clerical staff member's time, valued at $26.14 per hour will be required to incorporate the specific information into the notice and mail the estimated 13,000 notices. This

[134] The Departments' estimate is based on adjusted insurer claims and MEPS-HC expenditures.

[135] While plans could prepare their own notice, the Departments assume that the notices will be prepared by service providers. The Departments have previously estimated that there are 630 health insurers (460 providing coverage in the group market, and 490 providing coverage in the individual market.). These estimates are from NAIC 2007 financial statements data and the California Department of Managed Healthcare (2009), *at* *http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx*. Because the hour and cost burden is shared among the Departments of Labor/Treasury and the Department of Health and Human Services, the burden to prepare the notices is calculated using half the number of insurers (315).

results in an estimated hour burden of approximately 1,100 hours with an equivalent cost of $29,000. Therefore, the total hour burden of this notice requirement is 1,300 hours with an equivalent cost of $48,000.

The associated cost burden of the rule results from material and mailing cost to distribute the estimated 13,000 notices. The Department estimates that the notice will be one-page in length, material and print costs will be five cents per page, and postage will be 44 cents per notice resulting in a per notice cost of 49 cents. This leads to a total estimated cost burden of approximately $6,500 to distribute the notices.

Type of Review: New collection.

Agency: Department of Health and Human Services.

Title: Patient Protection and Affordable Care Act Enrollment Opportunity Notice Relating to Lifetime Limits

OMB Number: 0938–1094.

Affected Public: Business; State, Local, or Tribal Governments.

Respondents: 630.

Responses: 13,000.

Frequency of Response: One-time.

Estimated Total Annual Burden Hours: 1,300 hours.

Estimated Total Annual Burden Cost: $6,500.

b. ICR Regarding Affordable Care Act Notice Relating to Rescission

As discussed earlier in this preamble, PHS Act Section 2712 and these interim 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. These interim 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.

This analysis assumes that rescissions only occur in the individual health insurance market, because rescissions in the group market are rare. The Department estimates that there are approximately 7.1 million individual policy holders in the individual market during a year. A report on rescissions finds that 0.15 percent of policies were rescinded during the 2004 to 2008 time period.[136] Based on these numbers, the Department estimates that approximately 10,700 policies are rescinded during a year, which would result in 10,700 notices being sent to affected policyholders. The Department estimates that 15 minutes of legal profession time at $119 per hour would be required by the estimated 490 insurers in the individual market to prepare the notice and one minute per notice of clerical professional time at $26 per hour would be required to distribute the notice. This results in an hour burden of approximately 300 hours with an equivalent cost of approximately $19,200. The Department estimates that the cost burden associated with distributing the notices will be approximately $5,200.[137]

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

[136] NAIC Report "Rescission Data Call of the NAIC Regulatory Framework (B) Task Force" December 17, 2009. http://www.naic.org/documents/committees_b_regulatory_framework_rescission_data_call_report.pdf

[137] This estimate is based on an average document size of one page, $.05 cents per page material and printing costs, and $.44 cent postage costs.

Agency: Department of Health and Human Services.

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

OMB Number: 0938–1094.

Affected Public: For Profit Business.

Respondents: 490

Responses: 10,700.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 300 hours.

Estimated Total Annual Burden Cost: $5,200.

c. ICR Relating to Affordable Care Act Patient Protections Disclosure Requirement

As discussed above in the Department of Labor and Department of Treasury PRA section, these interim final regulations contains a disclosure requirement for non-grandfathered health plans or policies requiring the designation of a primary care physician or usually requiring a referral from a primary care physician before receiving care from a specialist. These requirements are information collection requirements under the PRA.

In order to satisfy the interim final regulations' patient protection disclosure requirement, the Department estimates that 14,000 State and local governmental plans will need to notify approximately 2.6 million policy holders of their plans' policy in regards to designating a primary care physician and for obstetrical or gynecological visits. An estimated 490 insurers providing coverage in the individual market will need to notify an estimated 55,000 policy holders of their policy in regards to designating a primary care physician and for obstetrical or

gynecological visits. These estimates are based on the assumption that 22 percent of group plans and 40 percent of individual policies will not have grandfathered health plan status in 2011.[138]

Because the interim final regulations provide model language for this purpose, the Department estimates that five minute of clerical time (with a labor rate of $26.14/hour) will be required to incorporate the required language into the plan document and ten minutes of a human resource professional's time (with a labor rate of $89.12/hour) will be required to review the modified language. [139] Therefore, the Department estimates that plans and insurers will incur a one-time hour burden of 3,500 hours with an equivalent cost of $239,000 to meet the disclosure requirement.

The Department assumes that only printing and material costs are associated with the disclosure requirement, because the interim final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. 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. This results in a cost burden of $42,000 ($0.05 per page*1/2 pages per notice * 1.7 million notices*0.62).

Plans that relinquish their grandfather status in subsequent years will also become subject to this notice requirement and incur a cost to prepare and distribute the notice in the year they relinquish their grandfather status. Policy holders of non-grandfathered policies in the individual

[138] The Department's estimate of the number of State and local governmental health plans was obtained from the 2007 Census of Governments. The estimate of the number of policy holders in the individual market were obtained from the 2009 Current Population Survey. Information on HMO and POS plans and enrollment in such plans was obtained from the Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2009. The methodology used to estimate the percentage of plans that will not be grandfathered in 2011 was discussed in Departments' Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act that were issued on June 15, 2010: 75 FR 34538 (June 17, 2010).

[139] EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

market will also have to receive this notice. The Department estimates a total hour burden of 2,500 hours in 2012 and 2,000 in 2013 for plans relinquishing their grandfather status in such years. There will, also be an estimated total cost burden of $30,000 in 2012 and $24,000 in 2013.

The Department notes 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: New collection.

Agency: Department of Health and Human Services.

Title: Disclosure Requirements for Patient Protection under the Affordable Care Act.

OMB Number: 0938–1094.

Affected Public: Business; State, Local, or Tribal Governments.

Respondents: 10,600.

Responses: 2,067,000.

Frequency of Response: One-time.

Estimated Total Annual Burden Hours: 2,700 hours.

Estimated Total Annual Burden Cost: $32,000.

If you comment on any of these information collection requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, OCIIO-9994-IFC

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

G. Congressional Review Act

These interim 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.) and have been transmitted to Congress and the Comptroller General for review.

H. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of $100 million (as adjusted for inflation) by State, local and tribal governments or the private sector. These interim final regulations are not subject to the Unfunded Mandates Reform Act because they are being issued as interim final regulations. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, the regulation 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.

I. 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 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 these 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' view, these interim final regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among various levels of government. However, in the Departments' view, the federalism implications of these interim 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 HIPAA requirements (including those of 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 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. State insurance laws that are more stringent than the Federal requirements are unlikely to ‘‘prevent the application of’’ the Affordable Care Act, and be preempted. 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 have engaged in efforts to consult with and work cooperatively with affected State and local officials, including 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 will act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of developing these interim final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Departments 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' 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 these interim final regulations, 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 regulations in a meaningful and timely manner.

V. Statutory Authority

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

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 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), Pub. L.104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 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.

26 CFR Part 602

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, 146, and 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller
Deputy Commissioner for Services and Enforcement,
Internal Revenue Service.

Approved: June 18, 2010

Michael F. Mundaca
Assistant Secretary of the Treasury (Tax Policy).

Signed this 18th day of June, 2010.

Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
Department of Labor

OCIIO-9994-IFC

Dated: June 18, 2010

Jay Angoff,

Director,

Office of Consumer Information and Insurance Oversight

Dated: June 18, 2010

Kathleen Sebelius,

Secretary ,
Department of Health and Human Services

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter 1

Accordingly, 26 CFR Parts 54 and 602 are amended as follows:

PART 54--PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 is amended by adding entries for §§54.9815-2704T, 54.9815-2711T, 54.9815-2712T, and 54.9815-2719AT in numerical order to read in part as follows:

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

Section 54.9815-2704T also issued under 26 U.S.C. 9833.
Section 54.9815-2711T also issued under 26 U.S.C. 9833.
Section 54.9815-2712T also issued under 26 U.S.C. 9833. * * *
Section 54.9815-2719AT also issued under 26 U.S.C. 9833. * * *

Par. 2. Section 54.9801-2 is amended by revising the definitions of group health plan and preexisting condition exclusion to read as follows:

§54.9801-2 Definitions.

* * * * *

Group health plan or plan means a group health plan within the meaning of §54.9831-1(a).

* * * * *

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 paragraph (a)(1)(i) to read as follows:

§54.9801-3 Limitations on preexisting condition exclusion period.

(a) * * *

(1) * * *

(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning set forth in §54.9801-2.

* * * * *

Par. 4. Section 54.9815-2704T is added to read as follows:

§54.9815-2704T Prohibition of preexisting condition exclusions (temporary).

(a) No preexisting condition exclusions--(1) In general. 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).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see §54.9801-3(a)(1)(ii)):

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

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

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

(ii) Conclusion. 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.

(b) Effective/applicability date--(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014.

(2) Early applicability date for children. The rules of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See §54.9815-1251T for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions).

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

Example. (i) Facts. Individual F commences employment and enrolls F and F's 16-year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

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

(c) Expiration date. This section expires on June 21, 2013.

Par. 5. Section 54.9815-2711T is added to read as follows:

§54.9815-2711T No lifetime or annual limits (temporary).

(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 benefits for any individual.

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

(ii) Exception for health flexible spending arrangements. A health flexible spending arrangement (as defined in section 106(c)(2)) 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.

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

(i) For a plan year beginning on or after September 23, 2010, but before September 23, 2011, $750,000.

(ii) For a plan year beginning on or after September 23, 2011, but before September 23, 2012, $1,250,000.

(iii) For plan years beginning on or after September 23, 2012, but before January 1, 2014, $2,000,000.

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

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

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

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

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

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

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

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

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

special enrollee, as provided under the rules of §54.9801-6(d). Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

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

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

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

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

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

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

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

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

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

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

(ii) Conclusion. In this Example 5, Q complies with the requirements of this paragraph (e). However, Q's choice to lower its annual limit means that under §54.9815-1251T(g)(1)(vi)(C), the group health plan will cease to be a grandfathered health plan and will be generally subject to all of the provisions of PHS Act sections 2701 through 2719A.

(f) Effective/applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See §54.9815-1251T for determining the application of this section to grandfathered health plans (providing that the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits).

(g) Expiration date. This section expires on June 21, 2013.

Par. 6. Section 54.9815-2712T is added to read as follows:

§54.9815-2712T Rules regarding rescissions (temporary).

(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 unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group 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; or

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

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

Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. 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) Effective/applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See §54.9815-1251T for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

(d) Expiration date. This section expires on June 21, 2013.

Par. 7. Section 54.9815-2719AT is added to read as follows:

§54.9815-2719AT Patient protections (temporary).

(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) 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 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.

(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 equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the

participant 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) 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) Effective/applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See §54.9815-1251T for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to grandfathered health plans).

(d) Expiration date. This section expires on June 21, 2013.

Par. 8. The authority citation for part 602 continues to read in part as follows:

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

Par. 9. Section 602.101(b) is amended by adding the following entries in numerical order to the table to read as follows:

§602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * * * *	
54.9815-2711T	1545-2179
54.9815-2712T	1545-2180
* * * * * * *	
54.9815-2719AT	1545-2181
* * * * * * *	

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For reasons stated in the preamble, EBSA amends 29 CFR Part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

1. 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), Pub. L.104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Secretary of Labor's Order 6-2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

2. 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.

* * * * *

3. Section 2590.701-3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701-3 Limitations on preexisting condition exclusion period.

(a) * * *

(1) * * *

(i) A preexisting condition exclusion means a preexisting condition exclusion within the meaning set forth in § 2590.701-2 of this part.

* * * * *

4. Section 2590.715-2704 is added to subpart C to read as follows:

§ 2590.715-2704 Prohibition of preexisting condition exclusions.

(a) No preexisting condition exclusions—(1) In general. 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 of this part).

(2) Examples. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 2590.701-3(a)(1)(ii) of this part):

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

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

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

(ii) Conclusion. 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.

(b) Applicability—(1) General applicability date. Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014.

(2) Early applicability date for children. The rules of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010.

(3) Applicability to grandfathered health plans. See § 2590.715-1251 of this part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions).

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

Example. (i) Facts. Individual F commences employment and enrolls F and F's 16-year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes

a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

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

5. Section 2590.715-2711 is added to subpart C 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 benefits for any individual.

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

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

(b) Construction—(1) Permissible limits on specific covered benefits. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group 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.

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

(i) For a plan year beginning on or after September 23, 2010, but before September 23, 2011, $750,000.

(ii) For a plan year beginning on or after September 23, 2011, but before September 23, 2012, $1,250,000.

(iii) For plan years beginning on or after September 23, 2012, but before January 1, 2014, $2,000,000.

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

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

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

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

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

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual written

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

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

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

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §2590.701-6(d) of this part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose

coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

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

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

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

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

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

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

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

individuals who enroll when first eligible. The plan would have to provide D and E the opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible, even if D had not switched to the low-cost benefit package option.

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

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

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

(ii) Conclusion. In this Example 5, Q complies with the requirements of this paragraph (e). However, Q's choice to lower its annual limit means that under §2590.715-1251(g)(1)(vi)(C), the group health plan will cease to be a grandfathered health plan and will be generally subject to all of the provisions of PHS Act sections 2701 through 2719A.

(f) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits).

6. Section 2590.715-2712 is added to subpart C 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 unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group 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; or

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

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

Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years previously. A is later diagnosed with breast cancer and seeks benefits under

the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

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

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

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

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

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

7. Section 2590.715-2719A is added to subpart C 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) 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 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.

(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 equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant 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) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) Facts. A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) Conclusion. In this Example 1, the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: one has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) Conclusion. In this Example 3, the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) Facts. Same facts as Example 3. Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) Facts. Same facts as Example 4. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) Conclusion. In this Example 5, the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- $116 -- excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) Facts. Same facts as Example 5. The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 6, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe

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

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

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

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

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

(c) Applicability date. The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715-1251 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to grandfathered health plans).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Consumer Information and Insurance Oversight

45 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR parts 144 and 146, and part 147, added May 13, 2010, at 75 FR 27138, effective July 12, 2010, as follows:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

1. 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.

2. 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.

* * * * *

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

3. Section 146.111(a)(1)(i) is revised to read as follows:

§ 146.111 Limitations on preexisting condition exclusion period.

(a) * * *

(1) * * *

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

* * * * *

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

4. The authority citation for part 147 continues to read as follows:

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

5. Add §147.108 to read as follows:

§ 147.108 Prohibition of preexisting condition exclusions.

(a) No preexisting condition exclusions—(1) In general. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103).

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

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

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

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

(ii) Conclusion. In this Example 2, M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

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

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

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

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

Example 1. (i) Facts. Individual F commences employment and enrolls F and F's 16-year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

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

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

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

6. Add § 147.126 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 benefits for any individual.

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

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

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

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

(c) Definition of essential health benefits. The term "essential health benefits" means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

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

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

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

(iii) For plan years (in the individual market, policy years) beginning on or after September 23, 2012, but before January 1, 2014, $2,000,000.

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

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

(d)(1) of this section if compliance with paragraph (d)(1) of this section would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage.

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

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

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

(2) Notice and enrollment opportunity requirements – (i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan – or group or individual health insurance coverage – described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual written notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, or if an enrolled individual is eligible for but not enrolled in any benefit package under the plan or health insurance coverage, then the plan and issuer must also give such an individual an opportunity to

enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.

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

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

(4) Treatment of enrollees in a group health plan. Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of §146.117(d). Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also

cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

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

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

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

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

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

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

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

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

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

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

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

Example 6. (i) Facts. For a policy year that began on October 1, 2009, Individual T has individual health insurance coverage with a lifetime limit on the dollar value of all benefits of $1 million. For the policy year beginning October 1, 2010, the issuer of T's health insurance coverage eliminates the lifetime limit and replaces it with an annual limit of $1 million dollars. In the policy year beginning October 1, 2011, the issuer of T's health insurance coverage maintains the annual limit of $1 million dollars.

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

(f) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits, and the prohibition on lifetime limits apply to individual health

insurance coverage that is a grandfathered health plan but the rules on annual limits do not apply to individual health insurance coverage that is a grandfathered health plan).

7. Add §147.128 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 unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a

cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

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

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

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

Example 1. (i) Facts. Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years previously. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

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

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

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

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

(c) Applicability date. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

8. Add §147.138 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) Example. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) Facts. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) Conclusion. In this Example, the plan has satisfied the requirements of paragraph (a) of this section.

(2) Designation of pediatrician as primary care provider—(i) In general. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) Construction. Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

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

Example 1. (i) Facts. A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) Conclusion. In this Example 1, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) Facts. Same facts as Example 1, except that A takes A's child to B for treatment of the child's severe shellfish allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) Conclusion. In this Example 2, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) Patient access to obstetrical and gynecological care—(i) General rights—(A) Direct access. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) Obstetrical and gynecological care. A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a

participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) Application of paragraph. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) Construction. Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

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

Example 1. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) Conclusion. In this Example 1, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) Facts. Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) Conclusion. In this Example 2, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) Facts. Same facts as Example 1 except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) Conclusion. In this Example 3, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) Facts. A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) Conclusion. In this Example 4, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) Notice of right to designate a primary care provider—(i) In general. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights –

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) Timing. In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) Model language. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

> [Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

> For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

> You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making

referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) Coverage of emergency services.—(1) Scope. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) General rules. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner –

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than –

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) Cost-sharing requirements – (i) Copayments and coinsurance. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) Other cost sharing. Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) Examples. The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) Facts. A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) Conclusion. In this Example 1, the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) Facts. A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) Conclusion. In this Example 2, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) Facts. A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: one has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) Conclusion. In this Example 3, the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) Facts. Same facts as Example 3. Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) Conclusion. In this Example 4, the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) Facts. Same facts as Example 4. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) Conclusion. In this Example 5, the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services -- $116 -- excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) Facts. Same facts as Example 5. The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) Conclusion. In this Example 6, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) Definitions. The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) Emergency medical condition. The term emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine,

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

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

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

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

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

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

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