

**VI. What references are on display?**

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Spiracur, Inc., November 3, 2008.

**List of Subjects in 21 CFR Part 878**

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

**PART 878—GENERAL AND PLASTIC SURGERY DEVICES**

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Section 878.4683 is added to subpart E to read as follows:

**§ 878.4683 Non-Powered suction apparatus device intended for negative pressure wound therapy.**

(a) *Identification.* A non-powered suction apparatus device intended for negative pressure wound therapy is a device that is indicated for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. It is further indicated for management of wounds, burns, flaps, and grafts.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)." See § 878.1(e) for the availability of this guidance document.

Dated: November 10, 2010.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2010-28873 Filed 11-16-10; 8:45 am]

**BILLING CODE 4160-01-P**

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

[TD 9506]

RIN 1545-BJ91

**DEPARTMENT OF LABOR****Employee Benefits Security Administration****29 CFR Part 2590**

RIN 1210-AB42

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of Consumer Information and Insurance Oversight****45 CFR Part 147**

RIN 0950-AA17

[OCIO-9991-IFC2]

**Amendment to the 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**

**AGENCY:** 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:** Amendment to interim final rules with request for comments.

**SUMMARY:** This document contains an amendment to 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 status as a grandfathered health plan; the amendment permits certain changes in policies, certificates, or contracts of insurance without loss of grandfathered status.

**DATES:** *Effective Date.* This amendment to the interim final regulations is effective on November 15, 2010.

*Comment Date.* Comments are due on or before December 17, 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 may be posted on the Internet and can be retrieved by most Internet search engines. Comments may be submitted anonymously.

*Department of Labor.* Comments to the Department of Labor, identified by RIN 1210-AB42, by one of the following methods:

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

- *E-mail:* [E-OHPSCA1251amend.EBSA@dol.gov](mailto:E-OHPSCA1251amend.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-AB42.

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 OCIO-9991-IFC2. 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: OCIO-9991-IFC2, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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: OCIO-

9991-IFC2, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

- *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 the following address: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9991-IFC2, 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 OCIO 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.)

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

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-118412-10, 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-118412-10), 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-118412-10), 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; Lisa Campbell, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (301) 492-4100.

*Customer Service Information:* Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<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) Web site ([http://www.cms.hhs.gov/HealthInsReformforConsumers/01\\_Overview.asp](http://www.cms.hhs.gov/HealthInsReformforConsumers/01_Overview.asp)) and the Office of Consumer Information & Insurance Oversight (OCIO) Web site (<http://www.hhs.gov/OCIO>).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions in 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.<sup>1</sup> 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,

<sup>1</sup>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," as used in those provisions, does not include self-insured group health plans.

changes. Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, specifies that certain plans or coverage existing as of the date of enactment (that is, grandfathered health plans) are subject to only certain provisions.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) previously issued interim final regulations implementing section 1251 of the Affordable Care Act; these interim final regulations were published in the **Federal Register** on June 17, 2010 (75 FR 34538). Additionally, on September 20, 2010,<sup>2</sup> October 8, 2010,<sup>3</sup> October 12, 2010,<sup>4</sup> and October 28, 2010,<sup>5</sup> the Departments issued subregulatory guidance on a number of issues pertaining to the implementation of the Affordable Care Act, including several clarifications relating to the interim final regulations on grandfathered health plans.

Section 1251 of the Affordable Care Act, as modified by section 10103 of the Affordable Care Act and section 2301 of the Reconciliation Act, provides that certain plans or coverage existing as of March 23, 2010 (the date of enactment of the Affordable Care Act) are subject to only certain provisions of the Affordable Care Act. The statute and the interim final regulations refer to these plans or health insurance coverage as grandfathered health plans. The statute and the interim final regulations provide that a group health plan or group or individual health insurance coverage is a grandfathered health plan with respect to individuals enrolled on March 23, 2010 regardless of whether an individual later renews the coverage. The interim final regulations specify certain changes to a plan or coverage that would cause it to no longer be a grandfathered health plan.

In addition, the statute and the interim final regulations provide that a group health plan that provided coverage on March 23, 2010 generally is also a grandfathered health plan with

<sup>2</sup>The subregulatory guidance took the form of "frequently asked questions" (FAQs). The September 20, 2010 FAQs are available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and <http://www.hhs.gov/ocio/regulations/questions.html>.

<sup>3</sup>The October 8, 2010 FAQs are available at <http://www.dol.gov/ebsa/faqs/faq-aca2.html> and [http://www.hhs.gov/ocio/regulations/implementation\\_faq.html](http://www.hhs.gov/ocio/regulations/implementation_faq.html).

<sup>4</sup>The October 12, 2010 FAQs are available at <http://www.dol.gov/ebsa/faqs/faq-aca3.html> and [http://www.hhs.gov/ocio/regulations/implementation\\_faq.html](http://www.hhs.gov/ocio/regulations/implementation_faq.html).

<sup>5</sup>The October 28, 2010 FAQs are available at <http://www.dol.gov/ebsa/faqs/faq-aca4.html> and [http://www.hhs.gov/ocio/regulations/implementation\\_faq.html](http://www.hhs.gov/ocio/regulations/implementation_faq.html).

respect to new employees (whether newly hired or newly enrolled) and their families that enroll in the grandfathered health plan after March 23, 2010. The interim final regulations clarify that, in such cases, any health insurance coverage provided under the group health plan in which an individual was enrolled on March 23, 2010 is also a grandfathered health plan.

Paragraph (g)(1) of the interim final regulations includes rules for determining when changes to the terms of a plan or health insurance coverage cause the plan or coverage to cease to be a grandfathered health plan. In addition to the changes described in paragraph (g)(1) of the interim final regulations that cause a plan to cease to be a grandfathered health plan, paragraph (a)(1)(ii) of the interim final regulations provides that if an employer or employee organization enters into a new policy, certificate, or contract of insurance after March 23, 2010, the policy, certificate, or contract of insurance is not a grandfathered health plan with respect to individuals in the group health plan. For example, under the interim final regulations, if a group health plan changes issuers after March 23, 2010, the group health plan ceases to be a grandfathered health plan, even if the plan otherwise would be a grandfathered health plan under the standards set forth in paragraph (g)(1).<sup>6</sup> In contrast, under the interim final regulations, a change in third-party administrator (TPA) by a self-insured group health plan does not cause the plan to relinquish grandfather status, provided that the change of TPA does not result in any other change that would cause loss of grandfather status under paragraph (g)(1).

## II. Overview of Amendment to the Interim Final Regulations

The Departments have received comments on paragraph (a)(1)(ii) of the interim final regulations, which provides that a group health plan will relinquish grandfather status if it changes issuers or policies. The comments expressed four principal concerns about this provision of the regulations. First, commenters raised

the concern that this provision treats insured group health plans, which cannot change issuers or policies without ceasing to be a grandfathered health plan, differently from self-insured group health plans, which can change TPAs without relinquishing grandfather status, as long as any other plan change (such as cost sharing or employer contributions) does not exceed the standards of paragraph (g)(1) of the interim final regulations. Second, commenters raised questions about circumstances in which a group health plan changes its issuer involuntarily (for example, the issuer withdraws from the market) yet the plan sponsor wants to maintain its grandfather status with a new issuer. Third, commenters noted that the provision would unnecessarily restrict the ability of issuers to reissue policies to current plan sponsors for administrative reasons unrelated to any change in the underlying terms of the health insurance coverage (for example, to transition the policy to a subsidiary of the original issuer or to consolidate a policy with its various riders or amendments) without loss of grandfather status. Finally, commenters expressed concern that the provision terminating grandfather status upon any change in issuer gives issuers undue and unfair leverage in negotiating the price of coverage renewals with the sponsors of grandfathered health plans, and that this interferes with the health care cost containment that tends to result from price competition.

The interim final regulations issued on June 17, 2010 were based on an interpretation of the language in section 1251 of the Affordable Care Act providing that grandfather status is based on “coverage under a group health plan or health insurance coverage in which such individual was enrolled on the date of the enactment of the Act.” In adopting the interim final regulations, the Departments did not consider a new insurance policy issued after March 23, 2010 to be a grandfathered health plan (except for the special rule for a group health plan maintained pursuant to a collective bargaining agreement) because “coverage” under the new policy was not in place on that date.

Following review of the comments submitted on this issue and further review and consideration of the provisions of section 1251 of the Affordable Care Act, the Departments have determined it is appropriate to amend the interim final regulations to allow a group health plan to change health insurance coverage (that is, to allow a group health plan to enter into a new policy, certificate, or contract of insurance) without ceasing to be a

grandfathered health plan, provided that the plan continues to comply fully with the standards set forth in paragraph (g)(1). For purposes of section 1251 of the Affordable Care Act, the Departments now conclude that it is reasonable to construe the statutory term “group health plan” to apply the grandfather provisions uniformly to both self-insured and insured group health plans (and, consequently, to health insurance coverage offered in connection with a group health plan). Where insured coverage is provided not through a group health plan but instead in the individual market, a change in issuer would still be a change in the health insurance coverage in which the individual was enrolled on March 23, 2010, and thus the new individual policy, certificate, or contract of insurance would not be a grandfathered health plan.

This amendment modifies paragraph (a)(1) of the interim final regulations, which previously caused a group health plan to cease to be a grandfathered health plan if the plan entered into a new policy, certificate, or contract of insurance. The modification provides that a group health plan does not cease to be grandfathered health plan coverage merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010<sup>7</sup> (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). The amendment applies to such changes to group health insurance coverage that are effective on or after November 15, 2010, the date the amendment to the interim final regulations was made available for public inspection; the amendment does not apply retroactively to such changes to group health insurance coverage that were effective before this date.<sup>8</sup> For this purpose, the date the new coverage becomes effective is the operative date, not the date a contract for a new policy, certificate or contract of insurance is entered into. Therefore, for example, if a plan enters into an agreement with an issuer on September 28, 2010 for a new policy to be effective on January 1, 2011, then January 1, 2011 is the date the new policy is effective and, therefore, the relevant date for purposes of determining the application of the

<sup>6</sup> In accordance with statutory provisions relating to collectively bargained group health plans, the interim final regulations include an exception for a group health plan governed by a collective bargaining agreement that was in effect on March 23, 2010. In such a case, the grandfathered group health plan is permitted to change issuers, or change from a self-insured plan to an insured plan, or make a change described under paragraph (g)(1) of the interim final regulations (which would otherwise end grandfather status) and remain a grandfathered health plan for the remainder of the duration of the collective bargaining agreement.

<sup>7</sup> Of course, with respect to changes to group health insurance coverage on or after March 23, 2010 but before June 14, 2010, the Departments' enforcement safe harbor remains in effect for good faith efforts to comply with a reasonable interpretation of the statute.

<sup>8</sup> As noted below, the Departments are inviting comments on this amendment to the interim final regulations.

amendment to the interim final regulations. If, however, the plan entered into an agreement with an issuer on July 1, 2010 for a new policy to be effective on September 1, 2010, then the amendment would not apply and the plan would cease to be a grandfathered health plan.

Notwithstanding the ability to change health insurance coverage pursuant to the modification made by the amendment, if the new policy, certificate, or contract of insurance includes changes described in paragraph (g)(1) of the interim final regulations, the plan ceases to be a grandfathered health plan. In applying this amendment, as with other provisions of the interim final regulations, the rules apply separately to each benefit package made available under a group health plan.

The amendment also provides that, to maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health coverage sufficient to determine whether any change described in paragraph (g)(1) is being made. This documentation may include a copy of the policy or summary plan description. The amendment also makes minor conforming changes to other provisions of the interim final regulations.

Thus, a plan can retain its grandfather status if it changes its carrier, so long as it has not made any other changes that would revoke its status. This amendment is being issued on an interim final basis to notify plans as soon as possible of the change and is effective prospectively to minimize disruption to participants and beneficiaries. The Departments are continuing to review and evaluate the comments received in response to the June 17, 2010 interim final regulations. In addition, the Departments invite comments on this amendment to the interim final regulations, including the prospective effective date of the rule and how that affects plans with different plan years. Final regulations on grandfathered health plans will be published in the near future.

### III. Interim Final Rules and Waiver of Delay of Effective Date

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. The rule set forth in this amendment governs the applicability of the requirements in these sections and is therefore appropriate to carry them out. Therefore, the foregoing interim final rule authority applies to this amendment.

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. Although 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, 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 of this amendment to the June 17, 2010 interim final regulations in place until an additional public notice and comment process was completed.

As noted in the preamble to the June 17, 2010 interim final regulations, 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. Because grandfathered health plans are exempt from many of these provisions while group health plans and group and individual health insurance coverage that are not grandfathered health plans must comply with them, it was critical for plans and issuers to receive clear guidance as to whether they were so exempt as soon as possible; accordingly, the June 17, 2010 interim final regulations were published without prior notice and comment. While the Affordable Care Act provisions have become effective with respect to certain plans and coverage, the majority of plans and coverage have not yet become subject to the Act. It is critical to provide those plans with the guidance in these interim final rules immediately. In addition, the provisions of this amendment essentially are the product of prior notice and comment, as

they are a logical outgrowth of the June 17, 2010 interim final regulations which provided an opportunity for public comment, and are being issued in response to public comments received.

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 regulations into effect, and that it is in the public interest to promulgate interim final regulations.

In addition, under Section 553(d) of the APA, regulations are to be published at least 30 days before they take effect. Again, under section 553(d)(3), this requirement may be waived “for good cause found and published with the rule.” For the reasons set forth above, the Departments have determined that there is good cause for waiver of the 30 day delay of effective date requirement in section 553(d).

### IV. Economic Impact and Paperwork Burden

#### A. Overview and Need for Regulatory Action—Department of Labor and Department of Health and Human Services

As stated earlier in this preamble, the Departments of Health and Human Services, Labor, and the Treasury (the Departments) previously issued interim final regulations implementing section 1251 of the Affordable Care Act that were published in the **Federal Register** on June 17, 2010 (75 FR 34538). Paragraph (a)(1)(ii) of the interim final regulations provides that if a group health plan changes the issuer providing the insured health coverage after March 23, 2010, the group health plan ceases to be a grandfathered health plan. Paragraph (g)(1) of the interim final regulations includes rules for determining when changes to the terms of a plan or health insurance coverage cause a plan or coverage to cease to be a grandfathered health plan.

As described earlier in this preamble, comments expressed a number of concerns regarding the change in issuer rule. Among other concerns, comments stated that the change in issuer rule provides issuers with undue leverage in negotiating the price of coverage renewals with grandfathered health plans, because a change in carrier would result in plans relinquishing their grandfathered status. Therefore, in effect, the provision could impede employers' efforts to obtain group health insurance coverage for their employees at the lowest cost. Commenters also expressed concern that the rule creates an unlevel playing field for self-insured

and fully-insured group health plans, because the former could change plan administrators without relinquishing their grandfathered health plan status, while the latter could not change issuers without relinquishing such status.

After reviewing the comments concerning this issue and further analyzing the statutory provision, the Departments have determined that it is appropriate to amend the interim final regulations to allow group health plans to change a health insurance policy or issuer providing health insurance coverage without ceasing to be a grandfathered health plan, provided that the standards set forth under paragraph (g)(1) of the interim final regulations are met. The Departments expect that this amendment will result in a small increase in the number of plans retaining their grandfathered status relative to the estimates made in the interim final regulations. The Departments did not produce a range of estimates for the number of affected entities given considerable uncertainty about the behavioral response to this amendment. For a further discussion, see Section II. Overview of Amendment to the Interim Final Regulations, above.

#### *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 amendment to the interim final regulations is significant within the meaning of section 3(f)(4) of the Executive Order. Accordingly, OMB has reviewed the amendment pursuant to the Executive Order.

#### *C. 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. 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. The interim final regulations were exempt from the 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 did not apply and the Departments were not required to either certify that the regulations or this amendment 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 amendment on small entities and believe that the amendment will have a positive impact on small plans, because such plans are more likely to be fully-insured. The Departments estimated in the regulatory impact analysis for the interim final regulations that small plans were more likely to relinquish grandfathered health plan status due to changes in issuers or policies than large plans. Therefore, this amendment to the interim final regulations will benefit small plans that want to retain their grandfathered health plan status while still changing health insurance issuers. This change should give employers greater flexibility to keep premiums affordable for the same plan.

#### *D. 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 Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these 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.

#### *E. Paperwork Reduction Act*

As part of their continuing efforts to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, and collection requirements on respondents can be properly assessed.

As discussed earlier in this preamble, the amendment to the interim final regulation adds a new disclosure requirement that requires the group health plan that is changing health insurance coverage to provide to the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph (g)(1) are exceeded. The Departments expect that this amendment will result in a small increase in the number of plans retaining their grandfathered status relative to the estimates made in the interim final regulations. Although the Departments did not produce a range of estimates for the number of affected entities due to the considerable uncertainty regarding the behavioral response to this amendment, the Departments estimate that the new disclosure requirement associated with the amendment will result in a total hour burden of 3,845 hours and a total cost burden of \$260,000.<sup>9</sup> The Departments welcome comments on this estimate.

The Office of Management and Budget has approved revisions to the ICRs contained under OMB Control Numbers

<sup>9</sup> The Departments applied the same methodology that was used in estimating the hour and cost burden associated with the information collection requests (ICRs) contained in the interim final regulations to make this estimate.

1210–0140 (Department of Labor), 1545–2178 (Department of the Treasury; Internal Revenue Service), and 0938–1093 (Department of Health and Human Services) reflecting this estimate. 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) 219–2745. These are not toll-free numbers. E-mail: [ebbsa.opr@dol.gov](mailto:ebbsa.opr@dol.gov). ICRs submitted to OMB also are available at [reginfo.gov](http://www.reginfo.gov/public/do/PRAMain) (<http://www.reginfo.gov/public/do/PRAMain>).

#### F. Congressional Review Act

This amendment to the interim final regulations is 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 has been transmitted to Congress and the Comptroller General for review. The interim final rule is not a “major rule” as that term is defined in 5 U.S.C. 804, because it does not result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

#### G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 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. This amendment to the interim final regulations is not subject to the Unfunded Mandates Reform Act, because they are being issued as an interim final regulation. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, this amendment to the interim final regulations 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.

#### H. 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, this amendment to the regulation has federalism implications, because it has 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 the regulation is 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 standard.

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 ERISA section 731 and PHS Act section 2724 (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 this amendment, 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 regulations, the Departments certify that the Employee Benefits Security Administration and the Office of Consumer Information and Insurance Oversight have complied with the requirements of Executive Order 13132 for the attached amendment to the interim final 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 Public Law 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 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

#### List of Subjects

##### 26 CFR Part 54

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

##### 29 CFR Part 2590

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

##### 45 CFR Part 147

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

Approved: November 8, 2010.

#### Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

#### Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 5th day of November 2010.

#### Phyllis C. Borzi,

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

Approved: November 9, 2010.

#### Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Approved: November 9, 2010.

#### Kathleen Sebelius,

Secretary, Department of Health and Human Services.

#### Department of the Treasury

Internal Revenue Service

26 CFR Chapter I

■ Accordingly, 26 CFR part 54 is amended as follows:

#### PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read in part as follows:

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

■ **Par. 2.** Section 54.9815–1251T is amended by:

- 1. Revising paragraph (a)(1).
- 2. Redesignating paragraphs (a)(3) introductory text, (a)(3)(i), and (a)(3)(ii) as paragraphs (a)(3)(i), (a)(3)(i)(A) and (a)(3)(i)(B), respectively.
- 3. Adding new paragraph (a)(3)(ii).
- 4. Removing paragraphs (a)(5) and (f)(2).
- 5. Redesignating paragraph (f)(1) as paragraph (f).
- 6. Revising the last sentence in newly-designated paragraph (f).
- 7. Revising paragraph (g)(4) *Example 9*.

The revisions and addition reads as follows:

#### § 54.9815–1251T Preservation of right to maintain existing coverage (temporary).

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage.* *Grandfathered health plan coverage* means coverage provided by a group health plan, or a health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and

(g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

\* \* \* \* \*

(3)(i) \* \* \*

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

\* \* \* \* \*

(f) \* \* \* After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) \* \* \*

(4) \* \* \*

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

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

#### Department of Labor

Employee Benefits Security Administration

29 CFR Chapter XXV

■ 29 CFR part 2590 is amended 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).

■ 2. Section 2590.715–1251 is amended by:

- 1. Revising paragraph (a)(1).
- 2. Redesignating paragraphs (a)(3), (a)(3)(i) and (a)(3)(ii) as paragraphs (a)(3)(i), (a)(3)(i)(A) and (a)(3)(i)(B), respectively.
- 3. Adding new paragraph (a)(3)(ii).
- 4. Removing paragraphs (a)(5) and (f)(2).
- 5. Redesignating paragraph (f)(1) as paragraph (f).
- 6. Revising the last sentence in newly-designated paragraph (f).
- 7. Revising paragraph (g)(4) *Example 9*.

The revisions and addition reads as follows:

### § 2590.715–1251 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage*. *Grandfathered health plan coverage* means coverage provided by a group health plan, or a health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For

purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage.

(ii) *Changes in group health insurance coverage*. Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

\* \* \* \* \*

(3)(i) \* \* \*  
(ii) *Change in group health insurance coverage*. To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

\* \* \* \* \*

(f) \* \* \* After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) \* \* \*  
(4) \* \* \*

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

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

separately under the rules of this paragraph (g).

## Department of Health and Human Services

### 45 CFR Chapter I

■ Accordingly, 45 CFR part 147 is amended as follows:

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

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

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

■ 2. Section 147.140 is amended by:

- 1. Revising paragraph (a)(1).
- 2. Redesignating paragraphs (a)(3), (a)(3)(i) and (a)(3)(ii) as paragraphs (a)(3)(i), (a)(3)(i)(A) and (a)(3)(i)(B), respectively.
- 3. Adding new paragraph (a)(3)(ii).
- 4. Removing paragraphs (a)(5) and (f)(2).
- 5. Redesignating paragraph (f)(1) as paragraph (f).
- 6. Revising the last sentence in newly-designated paragraph (f).
- 7. Revising paragraph (g)(4) *Example 9*.

The revisions and addition reads as follows:

### § 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage*. *Grandfathered health plan coverage* means coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for

example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

\* \* \* \* \*

(3)(i) \* \* \*

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

\* \* \* \* \*

(f) \* \* \* After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) \* \* \*

(4) \* \* \*

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

(ii) *Conclusion.* In this *Example 9*, the coverage under Option *H* is not grandfathered health plan coverage as of July

1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

[FR Doc. 2010-28861 Filed 11-15-10; 4:15 pm]

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## DEPARTMENT OF JUSTICE

### Office of the Attorney General

#### 28 CFR Part 0

[AG Order No. 3229-2010]

#### Office of Tribal Justice

AGENCY: Department of Justice.

ACTION: Final rule.

**SUMMARY:** This rule will amend part 0 of title 28 of the Code of Federal Regulations to reflect the establishment of the Office of Tribal Justice as a distinct component of the Department of Justice. The Office of Tribal Justice was created by the Attorney General to provide a channel for Tribes to communicate their concerns to the Department, to help coordinate policy on Indian affairs both within the Department and with other Federal agencies, and to ensure that the Department and its components work with Tribes on a government-to-government basis. This rule, which sets forth the Office's organization, mission and functions, amends the Code of Federal Regulations in order to reflect accurately the Department's internal management structure.

**DATES:** *Effective Date:* November 17, 2010.

**FOR FURTHER INFORMATION CONTACT:** Tracy Toulou, Director, Office of Tribal Justice, U.S. Department of Justice, RFK Main Justice Building, Room 2318, 950 Pennsylvania Avenue, NW., Washington, DC 20530. Telephone: (202) 514-8812.

#### SUPPLEMENTARY INFORMATION:

##### Background

In 1995 the Attorney General established the Office of Tribal Justice (OTJ) to provide a principal point of contact within the Department of Justice to listen to the concerns of Indian tribes and other parties interested in Indian affairs and to communicate the Department's policies to the Tribes and the public; to promote internal uniformity of Department of Justice policies and litigation positions relating to Indian country; and to coordinate with other Federal agencies and with

State and local governments on their initiatives in Indian country. On November 5, 2009, the President directed all Federal agencies to develop a consultation and coordination policy that ensures effective communication with Tribes. The Director of OTJ, in consultation with Tribes and with other Department components, developed the Department's comprehensive plan in response to the President's directive, and is designated as the Department official responsible for following through on the plan and reporting requirements associated with the President's directive. The Director of OTJ also is the Department official responsible for certifying to the Office of Management and Budget that the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, have been met with regard to any regulation or legislation proposed by the Department.

On July 29, 2010, President Obama signed into law the Tribal Law and Order Act of 2010, Public Law 111-211. Section 214 of the Tribal Law and Order Act amends title I of the Indian Tribal Justice Technical and Legal Assistance Act of 2000, to provide that "[n]ot later than 90 days after the date of enactment of the Tribal Law and Order Act of 2010, the Attorney General shall establish the Office of Tribal Justice as a component of the Department." This rule implements fully that statutory directive.

#### Administrative Procedure Act 5 U.S.C. 553

This rule is a rule of agency organization and procedure, and relates to the internal management of the Department of Justice. It is therefore exempt from the requirements of notice and comment and a delayed effective date. 5 U.S.C. 553(b), (d).

#### Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule and by approving it certifies that this rule will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Department. Further, a Regulatory Flexibility Analysis was not required to be prepared for this final rule since the Department was not required to publish a general notice of proposed rulemaking for this matter.

#### Executive Order 12866

This action has been drafted and reviewed in accordance with Executive