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DEPARTMENT OF THE TREASURY

Internal Revenue Service

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CMS-9993-IFC2

45 CFR Part 147

RIN 0938-AQ66

Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes

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

ACTION: Amendment to interim final rules with request for comments.

SUMMARY: This document contains amendments to interim final regulations implementing the requirements regarding internal claims and appeals and external review processes for group

health plans and health insurance coverage in the group and individual markets under provisions of the Affordable Care Act. These rules are intended to respond to feedback from a wide range of stakeholders on the interim final regulations and to assist plans and issuers in coming into full compliance with the law through an orderly and expeditious implementation process.

DATES: Effective date. This amendment to the interim final regulations is effective on [**INSERT DATE 30 DAYS AFTER FILING FOR PUBLIC INSPECTION**].

Comment date. Comments are due on or before [**INSERT DATE 30 DAYS AFTER PUBLICATION IN FEDERAL REGISTER**].

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-AB45, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Email: E-OHPSCA2719amend.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-AB45.

Comments received by the Department of Labor will be posted without change to www.regulations.gov and 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 CMS-9993-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):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9993-IFC2,

P.O. Box 8010,

Baltimore, MD 21244-8010.

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

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9993-IFC2,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. 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:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, S.W.,

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 CMS 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.)

b. 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 telephone number (410) 786-9994 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.

Internal Revenue Service. Comments to the IRS, identified by REG-125592-10, 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-125592-10), 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-125592-10), 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; Ellen Kuhn, Centers for Medicare & Medicaid Services, 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 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). Information on health reform can be found at www.healthcare.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act, Public Law 111-152, was enacted on March 30, 2010 (collectively known as the "Affordable Care Act"). The Affordable Care Act reorganizes, amends, and adds 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.[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.

[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", as used in those provisions, does not include self-insured group health plans.

PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

On July 23, 2010, the Departments of Health and Human Services (HHS), Labor, and the Treasury (the Departments) issued interim final regulations implementing PHS Act section 2719 at 75 FR 43330 (July 2010 regulations), regarding internal claims and appeals and external review processes for group health plans and health insurance issuers offering coverage in the group and individual markets. The requirements of PHS Act section 2719 and the July 2010 regulations do not apply to grandfathered health plans under section 1251 of the Affordable Care Act.[2]

A. Internal Claims and Appeals

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

[2] The Departments published interim final regulations implementing section 1251 of the Affordable Care Act on June 17, 2010, at 75 FR 34538, as amended on November 17, 2010 at 75 FR 70114.

The July 2010 regulations provided such updated standards for compliance and invited comment on the updated standards. In particular, the July 2010 regulations provided the following additional standards[3] for internal claims and appeals processes:

1. The scope of adverse benefit determinations eligible for internal claims and appeals includes a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at the time).[4]
2. Notwithstanding the rule in the DOL claims procedure regulation that provides for notification in the case of urgent care claims[5] not later than 72 hours after the receipt of the claim, a plan or issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a claim involving urgent care as soon as possible, taking into account the medical exigencies, but not later than 24 hours after the receipt of the claim by the plan or issuer.[6]
3. Clarifications with respect to full and fair review, such that plans and issuers are clearly required to provide the claimant (free of charge) with new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan or issuer in

[3] To address certain relevant differences in the group and individual markets, the July 2010 regulations provided that health insurance issuers offering individual health insurance coverage must comply with three additional requirements for internal claims and appeals processes. First, the July 2010 regulations include initial eligibility determinations in the individual market within the scope of claims eligible for internal appeals. Second, health insurance issuers offering individual health insurance coverage are permitted only one level of internal appeal. Third, health insurance issuers offering individual health insurance coverage must maintain all records of claims and notices associated with internal claims and appeals for six years and must make these records available for examination by the claimant, State or Federal oversight agency. 75 FR 43330, 43334 (July 23, 2010).

[4] This definition is broader than the definition in the DOL claims procedure regulation, which provides that a denial, reduction, or termination of, or a failure to provide payment (in whole or in part) for a benefit is an adverse benefit determination eligible for internal claims and appeals processes.

[5] A claim involving urgent care is generally a claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function; or, in the opinion of the physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

[6] Under the July 2010 regulations, there is a special exception if the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan.

connection with the claim, as well as any new or additional rationale for a denial at the internal appeals stage, and a reasonable opportunity for the claimant to respond to such new evidence or rationale.

4. Clarifications regarding conflicts of interest, such that decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to an individual, such as a claims adjudicator or medical expert, must not be based upon the likelihood that the individual will support the denial of benefits.
5. Notices must be provided in a culturally and linguistically appropriate manner, as required by the statute, and as set forth in paragraph (e) of the July 2010 regulations.
6. Notices to claimants must provide additional content. Specifically:
    a. Any notice of adverse benefit determination or final internal adverse benefit determination must include information sufficient to identify the claim involved, including the date of the service, the health care provider, the claim amount (if applicable), the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning.
    b. The plan or issuer must ensure that the reason or reasons for an adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a final internal adverse benefit determination, this description must also include a discussion of the decision.

c. The plan or issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

d. The plan or issuer must disclose the availability of, and contact information for, an applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

7. If a plan or issuer fails to strictly adhere to all the requirements of the July 2010 regulations, the claimant is deemed to have exhausted the plan's or issuer's internal claims and appeals process, regardless of whether the plan or issuer asserts that it has substantially complied, and the claimant may initiate any available external review process or remedies available under ERISA or under State law.

On September 20, 2010, based on a preliminary review of comments from stakeholders which indicated that they believed more time was needed to come into compliance with PHS Act section 2719 and the additional internal claims and appeal standards in the July 2010 regulations, the Department of Labor issued Technical Release 2010-02 (T.R. 2010-02), which set forth an enforcement grace period until July 1, 2011 for compliance with certain new provisions with respect to internal claims and appeals.[7]

Specifically, T.R. 2010-02 set forth an enforcement grace period until July 1, 2011 with respect to standard #2 above (regarding the timeframe for making urgent care claims decisions), standard #5 above (regarding providing notices in a culturally and linguistically appropriate manner), standard #6 above (requiring broader content and specificity in notices), and standard #7 above (regarding exhaustion). T.R. 2010-02 also stated that, during that period, the

[7] Technical Release 2010-02 is available at http://www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-02.pdf. HHS published a corresponding guidance document, available at: http://cciio.cms.gov/resources/files/interim_procedures_for_internal_claims_and_appeals.pdf.

Department of Labor and the Internal Revenue Service (IRS) would not take any enforcement action against a group health plan, and HHS would not take any enforcement action against a self-funded nonfederal governmental health plan that is working in good faith to implement such additional standards but does not yet have them in place.[8]

Based on further review of the comments received on the July 2010 regulations and T.R. 2010-02, and other feedback from interested stakeholders, on March 18, 2011, the Department of Labor issued Technical Release 2011-01[9] (T.R. 2011-01), which modified and extended the enforcement grace period set forth in T.R. 2010-02. Specifically, T.R. 2011-01 extended the enforcement grace period until plan years beginning on or after January 1, 2012 with respect to standard #2 above (regarding the timeframe for making urgent care claims decisions), standard #5 above (regarding providing notices in a culturally and linguistically appropriate manner), and standard #7 above (regarding exhaustion). Moreover, whereas T.R. 2010-02 required plans to be working in good faith to implement such standards for the enforcement grace period to apply, T.R. 2011-01 stated that no such requirement would apply for either the extended or the original enforcement grace period.

With respect to standard #6 above (requiring broader content and specificity in notices), T.R. 2011-01 extended the enforcement grace period only in part. Specifically, with respect to the requirement to disclose diagnosis codes and treatment codes (and their corresponding meanings), T.R. 2011-01 extended the enforcement grace period until plan years beginning on or after January 1, 2012.[10] With respect to the other disclosure requirements of standard #6, the

[8] T.R. 2010-02 also stated that HHS was encouraging States to provide similar grace periods with respect to issuers and HHS would not cite a State for failing to substantially enforce the provisions of part A of title XXVII of the PHS Act in these situations.

[9] T.R. 2011-01 is available at http://www.dol.gov/ebsa/pdf/tr11-01.pdf.

[10] Information related to diagnosis and treatment codes (and/or their meanings) is, however, generally required to be provided to claimants upon request under existing DOL claims procedures. See 29 CFR 2560.503-1(h)(2)(iii), which is also applicable to plans (whether or not they are ERISA plans) and issuers that are not grandfathered health

enforcement grace period was extended from July 1, 2011 until the first day of the first plan year beginning on or after July 1, 2011 (which is January 1, 2012 for calendar year plans), affecting: (a) the disclosure of information sufficient to identify a claim (other than the diagnosis and treatment information), (b) the reasons for an adverse benefit determination, (c) the description of available internal appeals and external review processes, and (d) for plans and issuers in States in which an office of health consumer assistance program or ombudsman is operational, the disclosure of the availability of, and contact information for, such program. [11]

T.R. 2011-01 also stated the Departments' intent to issue an amendment to the July 2010 regulations that would take into account comments and other feedback received from stakeholders and make modifications to certain provisions of the July 2010 regulations. T.R. 2011-01 went on to state that the relief was intended to act as a bridge until an amendment to the July 2010 regulations was issued.

This amendment to the July 2010 regulations makes changes with respect to the provisions subject to the enforcement grace period under T.R. 2011-01. At the expiration of the enforcement grace period, the Departments will begin enforcing the relevant requirements of the July 2010 regulations, as amended by this rulemaking.

B. External Review

1. Applicability of Federal and State external review processes.

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plans pursuant to paragraph (b)(2)(i) of the July 2010 regulations. Nevertheless, a request for such information, in itself, should not be considered to be a request for (and therefore trigger the start of) an internal appeal or external review.

[11] Any enforcement grace period with respect to disclosure requirements that has been provided under T.R. 2010-02 or T.R. 2011-01 does not affect disclosure requirements still in effect for ERISA plans under the DOL claims procedure regulation and/or Part 1 of ERISA.

PHS Act section 2719, the July 2010 regulations, and technical guidance issued by the Departments[12] provide a system with respect to applicability of either a State external review process or a Federal external review process for non-grandfathered plans and issuers. How this impacts plans and issuers varies, depending on the type of coverage:

a. Self-insured plans subject to ERISA and/or the Code.

In the case of self-insured plans subject to ERISA and/or the Code, a Federal external review process supervised by DOL and Treasury applies (the "private accredited IRO process"[13]). On August 23, 2010, the Department of Labor issued Technical Release 2010-01 (T.R. 2010-01), which set forth an interim enforcement safe harbor for self-insured plans not subject to a State external review process or to the HHS-supervised process (the "HHS-administered process").[14] This interim enforcement safe harbor essentially permits a private contract process under which plans contract with accredited independent review organizations (IROs) to perform reviews. Separate guidance being issued contemporaneous with the publication of this amendment makes adjustments to, and provides clarifications regarding, the operation of the private accredited IRO process.

b. Insured coverage.

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[12] See DOL Technical Release 2010-01, available at http://www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf ; HHS Technical Guidance issued August 26, 2010, available at http://cciio.cms.gov/resources/files/interim_appeals_guidance.pdf; and HHS Technical Guidance issued September 23, 2010, available at http://cciio.cms.gov/resources/files/technical_guidance_for_self_funded_non_fed_plans.pdf. Additional clarifications were provided in the form of frequently-asked questions (FAQs), available at http://www.dol.gov/ebsa/faqs/faq-aca.html and http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs.html#claims.

[13] For simplicity, the Federal external review process for self-insured plans subject to ERISA and/or the Code supervised by DOL and Treasury is referred to as the "private accredited IRO process" throughout this preamble. However, the interim procedures for Federal external review issued as DOL Technical Release 2010-01 also recognizes that States may choose to expand access to their State external review process to plans not subject to applicable State laws (such as self-insured ERISA plans) and allows those plans to meet their responsibilities to provide external review under PHS Act section 2719(b) by voluntarily complying with the provisions of that State external review process.

[14] HHS Technical Guidance issued August 26, 2010 provided that, for insured coverage, the Federal external review process would be fulfilled through the HHS-administered process.

In the case of health insurance issuers in the group and individual market, the July 2010 regulations set forth 16 minimum consumer protections based on the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners (NAIC) that, if provided by a State external review process, will result in the State's process applying in lieu of a Federal external review process. Moreover, for insured group health plans, as provided under paragraph (c)(1) of the July 2010 regulations, if a State external review process applies to and is binding on the plan's health insurance issuer under paragraph (c) of the July 2010 regulations (regarding State standards for external review), then the insured group health plan is not required to comply with either the State external review process or the Federal external review process. The July 2010 regulations provided a transition period for plan years (in the individual market, policy years) beginning before July 1, 2011, during which any existing State external review process will be considered sufficient (and will apply to health insurance issuers in that State). During the transition period, in States and territories without an existing State external review process (Alabama, Mississippi, and Nebraska, Guam, American Samoa, U.S. Virgin Islands and the Northern Mariana Islands), HHS guidance generally provided that health insurance issuers will participate in the HHS-administered process. As explained later in this preamble, this amendment to the July 2010 regulations modifies the transition period originally issued as part of the July 2010 regulations so that the last day of the transition period for all health insurance issuers offering group and individual health insurance coverage is December 31, 2011.

In addition, the July 2010 regulations provided that, following the conclusion of the transition period, health insurance issuers in a State that does not meet the minimum consumer protection standards set forth in paragraph (c) of the July 2010 regulations will participate in an external review process under Federal standards similar to the process under the NAIC Uniform

Model Act, such as the HHS-administered process. Separate guidance being issued contemporaneous with the publication of this amendment announces standards under which, until January 1, 2014, a State may also operate such an external review process under Federal standards similar to the process under the NAIC Uniform Model Act (an "NAIC-similar process"). Accordingly, if HHS determines that a State has neither implemented the minimum consumer protections required under paragraph (c) of the July 2010 regulations, nor an NAIC-similar process, issuers in the State will have the choice of participating in either the HHS-administered process or the private accredited IRO process. HHS is adopting this approach to permit States to operate their external review processes under standards established by the Secretary until January 1, 2014, avoiding unnecessary disruption, while States work to adopt an "NAIC-parallel process," consistent with the consumer protections set forth in paragraph (c) of the July 2010 regulations.

c. Self-insured, nonfederal governmental plans.

For self-insured, nonfederal governmental plans (which are subject to the PHS Act, but not ERISA or the Code), previous HHS guidance generally provided that they follow the private accredited IRO process.[15] (In States and territories that did not have an existing external review process (Alabama, Mississippi, and Nebraska, Guam, American Samoa, U.S. Virgin Islands and the Northern Mariana Islands), previous HHS guidance generally provided that such plans may choose to follow the HHS-administered process or follow the private accredited IRO process.) Separate guidance being issued contemporaneous with the publication of this amendment generally treats self-insured nonfederal governmental plans the same as health insurance issuers. That is, a State may temporarily operate such an external review process applicable to a self-insured nonfederal governmental plan under Federal standards similar to the process under the

[15] See HHS Technical Guidance issued September 23, 2010.

NAIC Uniform Model Act. If no such State-operated process exists, self-insured nonfederal governmental plans have the choice of participating in either the HHS-administered process or the private accredited IRO process.

2. Scope of claims eligible for external review.

While the process varies depending on the type of coverage, so does the scope of claims eligible for external review. That is, for insurance coverage and self-insured nonfederal governmental plans subject to a State external review process (either an NAIC-parallel process or an NAIC-similar process), the State determines the scope of claims eligible for external review.[16] For coverage subject to either the HHS-administered process or the private accredited IRO process, the July 2010 regulations provided that any adverse benefit determination (or final internal adverse benefit determination) could be reviewed unless it related to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan. As explained later in this preamble, this amendment to the July 2010 regulations modifies the scope of claims eligible for external review under the Federal external review process.

II. Overview of Amendments to the Interim Final Regulations

A. Internal Claims and Appeals

1. Expedited notification of benefit determinations involving urgent care (paragraph (b)(2)(ii)(B) of the July 2010 regulations).

[16] Under paragraphs (c)(2)(i) and (c)(2)(xvi) of the July 2010 regulations, State processes must provide external review for adverse benefit determinations (including final internal adverse benefit determinations) that are based on issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; or that involve experimental or investigational treatment. (A State external review process may also provide for external review of a broader scope of adverse benefit determinations.) At the same, time, paragraph (c)(3) of the July 2010 regulations provides a transition period during which a State external review process will be considered binding on an issuer (or a plan), in lieu of the requirements of any Federal external review process, even if the State process does not meet all the requirements of paragraph (c)(2) of the July 2010 regulations. That transition period is being modified by this amendment, as described below.

The July 2010 regulations provided that a plan or issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a claim involving urgent care (as defined in the DOL claims procedure regulation)[17] as soon as possible, taking into account the medical exigencies, but not later than 24 hours after the receipt of the claim by the plan or issuer, unless the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan or health insurance coverage. This was a change from the DOL claims procedure regulation, which generally requires a determination not later than 72 hours after receipt of the claim by a group health plan for urgent care claims. The preamble to the July 2010 regulations stated that the Departments expected electronic communication would enable faster decision-making than in the year 2000, when the DOL claims procedure regulation was issued.[18]

While some commenters supported the 24-hour rule (particularly consumer advocates and medical associations, including mental health providers who noted the 24-hour standard was especially important for people in psychiatric crisis), concerns were raised by many plans and issuers regarding the burden of a 24-hour turnaround. Some commenters argued that some of the claims constituting "urgent care" and thus qualifying for the expedited timeframe really do not need to be made within 24 hours. Moreover, a number of commenters highlighted that the 72-hour provision was intended only to serve as a "backstop"; as the general rule under both the July 2010 regulations and the DOL claims procedure regulation requires a decision as soon as possible consistent with the medical exigencies involved, making the change to a 24-hour

[17] Under the DOL claims procedure regulation, a "claim involving urgent care" is a claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function; or, in the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.
[18] 75 FR 43330, 43333 (July 23, 2010).

timeframe unnecessary for the most serious medical cases. Some commenters cited the Emergency Medical Treatment and Labor Act (EMTALA)[19], which generally requires hospitals to provide emergency care to individuals with or without insurance or preauthorization and, therefore, mitigates the need for expedited pre-service emergency claims determinations in many situations. Finally, some commenters stated that a firm 24-hour turnaround for urgent care claims will adversely affect claimants, as plans and issuers will not have sufficient time to properly review a claim, adversely affecting the quality of the review process in cases where the provider cannot be consulted in time, and leading to unnecessary denials of claims.

After considering the comments, and the costs and benefits of an absolute 24-hour decision-making deadline for pre-service urgent care claims, this amendment permits plans and issuers to follow the original rule in the DOL claims procedure regulation (requiring decision-making in the context of pre-service urgent care claims as soon as possible consistent with the medical exigencies involved but in no event later than 72 hours), provided that the plan or issuer defers to the attending provider with respect to the decision as to whether a claim constitutes "urgent care." At the same time, the Departments underscore that the 72-hour timeframe remains only an outside limit and that, in cases where a decision must be made more quickly based on the medical exigencies involved, the requirement remains that the decision should be made sooner than 72 hours after receipt of the claim.

2. Additional notice requirements for internal claims and appeals (paragraph (b)(2)(ii)(E) of the July 2010 regulations).

The July 2010 regulations also provided additional content requirements for any notice of adverse benefit determination or final internal adverse benefit determination. The July 2010 regulations required a plan or issuer to:

[19] 42 U.S.C. § 1395dd.

(a) Ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved. Under the July 2010 regulations, this information included the date of service, the health care provider, and the claim amount (if applicable)[20], as well as the diagnosis code (such as an ICD-9 code, ICD-10 code, or DSM-IV code)[21], the treatment code (such as a CPT code)[22], and the corresponding meanings of these codes.

(b) Ensure that the description of the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code (such as a CARC and RARC)[23] and its corresponding meaning. It must also include a description of the plan's or issuer's standard, if any, that was used in denying the claim (for example, if a plan applies a medical necessity standard in denying a claim, the notice must include a description of the medical necessity standard). In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(c) Provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(d) Disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist enrollees with the internal claims and appeals and external review processes.[24]

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[20] The amount of the claim may not be knowable or available at the time, such as in a case of preauthorization, or there may be no specific claim, such as in a case of rescission that is not connected to a claim.
[21] ICD-9 and ICD-10 codes refer to the International Classification of Diseases, 9th revision and 10th revision, respectively. The DSM-IV codes refer to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.
[22] CPT refers to Current Procedural Terminology.
[23] CARC refers to Claim Adjustment Reason Code and RARC refers to Remittance Advice Remark Code.
[24] To assist plans and issuers in making these disclosures, the Departments provided a current list of relevant consumer assistance programs and ombudsmen in the Appendix to T.R. 2011-01. Plans and issuers with July 1 plan years may rely upon the list in that Appendix when developing their notices of adverse benefit determination and final internal adverse benefit determination for plan years beginning on July 1, 2011. The Departments are committed to reviewing and updating this list. The first update is being made available contemporaneous with

Many comments received on the July 2010 regulations raised concerns about the additional content required to be included in the notices. Comments by a range of stakeholders, including plans, issuers, and consumer advocacy organizations focused heavily on the automatic provision of the diagnosis and treatment codes (and their meanings). Concerns were raised about privacy (because explanations of benefits (EOBs) often are sent to an individual who is not the patient, such as an employee who is the patient's spouse or parent), interference with the doctor-patient relationship,[25] and high costs.[26] More specifically, commenters highlighted that sensitive issues such as mental health treatments would be identified by specific treatment or diagnosis codes and that privacy concerns are magnified for adult dependents under age 26 who may be covered by their parent's health plan. Others pointed out that there are over 20,000 treatment and diagnosis codes in use today, presenting a costly administrative and operational challenge for plans and issuers. Comments also questioned the efficacy of providing the codes, which some argued are often very difficult for the average patient to understand.[27]

Other comments were received in support of the coding provisions. Consumer advocates commented positively on the requirement that denial notices include information for consumers about their right to appeal denials and the availability of state consumer assistance programs (CAPs) that will help consumers file appeals. There were also positive comments on the

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publication of this amendment. The first update is available (and any future updates will be made available) at www.dol.gov/ebsa/healthreform and http://cciio.cms.gov/programs/consumer/capgrants/index.html.

[25] Several commenters raised concerns that providers' initial or suspected diagnosis may not match the ultimate diagnosis or patients' perception of their diagnosis. One commenter gave the example of a patient who has a biopsy procedure. In that case, the patient would receive an EOB with an initial diagnosis code of cancer, however the results of the biopsy may rule out cancer. In that situation, the EOB can result in confusion and unnecessary mental anguish.

[26] In particular, comment letters cited concerns with respect to programming aspects of providing diagnosis codes at a time when plans and issuers are changing over from ICD-9 diagnosis codes to more extensive and technical ICD-10 codes.

[27] Several commenters noted that technical ICD-9 and/or ICD-10 codes can be confusing and/or cause worry. One commenter gave the example of a patient presenting with a white coating on his tongue, who is told not to worry and to brush the tongue with a toothbrush. The diagnosis code is 529.3, hypertrophy of tongue papillae, a term not used by the patient's doctor during the office visit and, therefore, prone to cause confusion and/or concern.

requirement to provide a rationale for the denial (including a description of the plan's or issuer's standard (such as "medical necessity"), if any, that was used denying the claim). With respect to the provision of coding information, some commented that this would be helpful to consumers because coding errors and missing coding information often are the basis for denying claims.

After considering all of the comments, and the costs and benefits of the additional disclosure, this amendment eliminates the requirement to automatically provide the diagnosis and treatment codes as part of a notice of adverse benefit determination (or final internal adverse benefit determination) and instead substitutes a requirement that the plan or issuer must provide notification of the opportunity to request the diagnosis and treatment codes (and their meanings) in all notices of adverse benefit determination (and notices of final internal adverse benefit determination), and a requirement to provide this information upon request.[28] This amendment also clarifies that, in any case, a plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for (and therefore trigger the start of) an internal appeal or external review.

3. Deemed exhaustion of internal claims and appeals processes (paragraph (b)(2)(ii)(F) of the July 2010 regulations).

The courts generally require claimants to exhaust administrative proceedings before going to court or seeking external review. When plans and issuers offer full and fair internal procedures for resolving claims, it is reasonable to insist that claimants first turn to those procedures before seeking judicial or external review of benefit denials. There is less justification, however, for insisting that a claimant exhaust administrative procedures that do not

[28] As discussed earlier, in footnote 9, information related to diagnosis and treatment codes (and/or their meanings) is, however, generally required to be provided to claimants upon request under existing DOL claims procedures, which is also incorporated in the July 2010 regulations. See 29 CFR 2560.503-1(h)(2)(iii) and paragraph (b)(2)(i) of the July 2010 regulations.

comply with the law. Accordingly, the July 2010 regulations permitted claimants to immediately seek review if a plan or issuer failed to "strictly adhere" to all of the July 2010 regulations' requirements for internal claims and appeals processes, regardless of whether the plan or issuer asserted that it "substantially complied" with the July 2010 regulations. The July 2010 regulations also clarified that, in such circumstances, the reviewing tribunal should not give special deference to the plan's or issuer's decision, but rather should resolve the dispute de novo. Consumer groups generally supported this "strict adherence" approach, but the approach received a number of negative comments from some issuers and plan sponsors, who advocate a "substantial compliance" approach.

The Departments continue to believe that claimants should not have to follow an internal claims and appeals procedure that is less than full, fair, and timely, as set forth in the July 2010 regulations. In response to comments, the Departments are retaining the general approach to this requirement, but this amendment also adds a new paragraph (b)(2)(ii)(F)(2) to the July 2010 regulations to provide an exception to the strict compliance standard for errors that are minor and meet certain other specified conditions. The new paragraph will also protect claimants whose attempts to pursue other remedies under paragraph (b)(2)(ii)(F)(1) of the interim final regulations are rejected by a reviewing tribunal. Under the amended approach, any violation of the procedural rules of the July 2010 regulations pertaining to internal claims and appeals would permit a claimant to seek immediate external review or court action, as applicable, unless the violation was:

(1) De minimis;

(2) Non-prejudicial;

(3) Attributable to good cause or matters beyond the plan's or issuer's control;

(4) In the context of an ongoing good-faith exchange of information; and

(5) Not reflective of a pattern or practice of non-compliance.

In addition, the claimant would be entitled, upon written request, to an explanation of the plan's or issuer's basis for asserting that it meets this standard, so that the claimant could make an informed judgment about whether to seek immediate review. Finally, if the external reviewer or the court rejects the claimant's request for immediate review on the basis that the plan met this standard, this amendment would give the claimant the right to resubmit and pursue the internal appeal of the claim.

4. Form and manner of notice (paragraph (e) of the July 2010 regulations).

PHS Act section 2719 requires group health plans and health insurance issuers to provide relevant notices in a culturally and linguistically appropriate manner. The July 2010 regulations set forth a requirement to provide notices in a non-English language based on separate thresholds of the number of people who are literate in the same non-English language. In the group market, the threshold set forth in the July 2010 regulations differs depending on the number of participants in the plan:

- For a plan that covers fewer than 100 participants at the beginning of a plan year, the threshold is 25 percent of all plan participants being literate only in the same non-English language.
- For a plan that covers 100 or more participants at the beginning of a plan year, the threshold is the lesser of 500 participants, or 10 percent of all plan participants, being literate only in the same non-English language.

These thresholds were adapted from the DOL regulations regarding style and format for a summary plan description, at 29 CFR 2520.102-2(c) for participants who are not literate in

English. For the individual market, the threshold is 10 percent of the population residing in the county being literate only in the same non-English language. The individual market threshold was generally adapted from the approach used under the Medicare Advantage program, which required translation of materials in languages spoken by more than 10 percent of the general population in a service area at the time the threshold was established.

Under the July 2010 regulations, if an applicable threshold is met with respect to a non-English language, the plan or issuer must provide the notice upon request in the non-English language. Additionally, the plan or issuer must include a statement in the English versions of all notices, prominently displayed in the non-English language, offering the provision of such notices in the non-English language. Finally, to the extent the plan or issuer maintains a customer assistance process (such as a telephone hotline) that answers questions or provides assistance with filing claims and appeals, the plan or issuer must provide such assistance in the non-English language.

Comments received in response to the July 2010 regulations raised several concerns about this requirement. One group of commenters stated that the thresholds for the group market were difficult to comply with, especially for small plans (where an individual or a small number of individuals could cause a plan to change status with respect to the threshold) and insured plans (where the issuer may be in a very difficult position to determine the English literacy of an employer's workforce). Some commenters stated that the threshold requirements for the group and individual markets should be consistent.

Other commenters were concerned with the high costs of compliance with this rule, particularly the "tagging and tracking requirement" to the extent that individuals who request a document in a non-English language would need to be "tagged" and "tracked" so that any future

notices would be provided automatically in the non-English language. Some of these commenters cited the high costs associated with implementing translation requirements pursuant to California State law and the low take-up rates of translated materials in California. Some commenters also cited the importance of having written translation of documents available (at a minimum, upon request), as well as having oral language services for customer assistance.

Following review of the comments submitted on this issue and further review and consideration of the provisions of PHS Act section 2719, the Departments have determined it is appropriate to amend the provisions of the July 2010 regulations related to the provision of notices in a culturally and linguistically appropriate manner. This amendment establishes a single threshold with respect to the percentage of people who are literate only in the same non-English language for both the group and individual markets. With respect to group health plans and health insurance issuers offering group or individual health insurance coverage, the threshold percentage of people who are literate only in the same non-English language will be set at 10 percent or more of the population residing in the claimant's county, as determined based on American Community Survey data published by the United States Census Bureau.[29] The Departments will update this guidance annually on their website if there are changes to the list of the counties determined to meet this 10 percent threshold for the county's population being literate only in the same non-English language.[30]

This amendment to the July 2010 regulations requires that each notice sent by a plan or issuer to an address in a county that meets this threshold include a one-sentence statement in the

[29] At the time of publication of this amendment, 255 U.S. counties (78 of which are in Puerto Rico) meet this threshold. The overwhelming majority of these are Spanish; however, Chinese, Tagalog, and Navajo are present in a few counties, affecting five states (specifically, Alaska, Arizona, California, New Mexico, and Utah). A full list of the affected U.S. counties in 2011 is included in Table 2 later in this preamble, under the heading, "IV. Economic Impact and Paperwork Burden."

[30] This information will be made available at www.dol.gov/ebsa/healthreform and http://cciio.cms.gov/.

relevant non-English language about the availability of language services. The Departments have provided guidance with sample sentences in the relevant languages in separate guidance being issued contemporaneous with the publication of this amendment. For ease of administration, some plans and issuers may choose to use a one-sentence statement for all notices within an entire State (or for a particular service area) that reflects the threshold language or languages in any county within the State or service area. For example, statewide notices in California could include the relevant one-sentence statement in Spanish and Chinese because, using the data from Table 2, Spanish meets the 10 percent threshold in Los Angeles County and 22 other counties and Chinese meets the 10 percent threshold in San Francisco County. This would be a permissible approach to meeting the rule under this amendment.

In addition to including a statement in all notices in the relevant non-English language, this amendment requires a plan or issuer to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request. For this purpose, plans and issuers are permitted to direct claimants to the same customer service telephone number where representatives can first attempt to address the consumer's questions with an oral discussion, but also provide a written translation upon request in the threshold non-English language. Finally, this amendment removes any "tagging and tracking" requirement that would have otherwise applied under the July 2010 regulations.

This amendment to the July 2010 regulations provides standards for providing culturally and linguistically appropriate notices that balance the objective of protecting consumers by providing understandable notices to individuals who speak primary languages other than English with the goal of simplifying information collection burdens on plans and issuers. (Note, nothing

in these regulations should be construed as limiting an individual's rights under Federal or State civil rights statutes, such as Title VI of the Civil Rights Act of 1964 (Title VI) which prohibits recipients of Federal financial assistance, including issuers participating in Medicare Advantage, from discriminating on the basis of race, color, or national origin. To ensure non-discrimination on the basis of national origin, recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by limited English proficient persons. For more information, see, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," available at http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/policyguidancedocument.html.)

The Departments welcome comments on this amendment, including whether it would be appropriate to include a provision in the final rules requiring health insurance issuers providing group health insurance coverage to provide language services in languages that do not meet the requisite threshold for an applicable non-English language, if requested by the administrator or sponsor of the group health plan to which the coverage relates. For example, if Chinese does not meet the 10 percent threshold in New York County, but an employer with a large Chinese-speaking population asks the health insurance issuer providing its group health insurance coverage to provide language services in Chinese (as described in the amendment), the Departments invite comment on what obligations should be imposed on the issuer, if any, to provide language services in Chinese.

B. External Review

1. Duration of transition period for State external review processes.

In general, if State laws do not meet the minimum consumer protections of the NAIC Uniform Model Act[31], as set forth in paragraph (c)(2) of the July 2010 regulations, insurance coverage (as well as self-insured nonfederal governmental plan and church plan coverage) is subject to the requirements of an external review process under Federal standards similar to the process under the NAIC Uniform Model Act, such as the HHS-administered process. Paragraph (c)(3) of the July 2010 regulations provided a transition period for plan years (in the individual market, policy years) beginning before July 1, 2011 in order to allow States time to amend their laws to meet or go beyond the minimum consumer protections of the NAIC Uniform Model Act set forth in paragraph (c)(2) of the July 2010 regulations. HHS has been working closely with States regarding enactment of laws to conform to paragraph (c)(2) and much progress has been made. However, enacting State legislation and regulations can often be a complex and time-consuming process. Accordingly, the Departments are modifying the transition period under paragraph (c)(3) of the July 2010 regulations so that the last day of the transition period is December 31, 2011 to give States, which are making substantial progress in implementing State external review processes that conform to paragraph (c)(2), the requisite time to complete that process. Because the July 2010 regulations would have ended the transition period for plan years (in the individual market, policy years) beginning on or after July 1, 2011, the Departments note that ending the transition period on December 31, 2011 will reduce the length of the transition period for plans and policies with plan years (in the individual market, policy years) beginning after January 1 but before July 1. When the July 2010 regulations were published, the Departments anticipated that issuers in every State that had not enacted laws to conform to paragraph (c)(2) of the July 2010 regulations would need to participate in the HHS-administered

[31] The NAIC Uniform Model Act in place on July 23, 2010 provides external review for claims involving medical necessity, appropriateness, health care setting, level of care, effectiveness (of a covered benefit), whether a treatment is experimental, and whether a treatment is investigational.

process. Now, the Departments have decided that issuers may continue to participate in a State external review process under Federal standards similar to the process under the NAIC Uniform Model Act (an NAIC-similar process), which the Departments anticipate will reduce market disruption when the transition period ends. Therefore, based on the Departments' concerns for making the consumer protections of the Affordable Care Act available without undue delay and for ensuring as much uniformity as possible in the availability of those protections regardless of the form of a consumer's health coverage, the Departments have decided to end the transition period on December 31, 2011. Therefore, this amendment to the July 2010 regulations provides that, before January 1, 2012, an applicable State external process will apply in lieu of the requirements of the Federal external review process. PHS Act section 2719(c) authorizes the Departments to deem an external review process "in operation as of the date of enactment" of the Affordable Care Act as compliant with the external review requirements of PHS Act section 2719(b). Through December 31, 2011, any currently effective State external review process satisfies the requirements of either PHS Act section 2719(c) or section 2719(b)(2). If there is no applicable State external review process, separate guidance being issued contemporaneous with the publication of this amendment generally provides a choice between the HHS-administered process or the private accredited IRO process.

2. Scope of the Federal External Review Process

Paragraph (d)(1) of the July 2010 regulations sets forth the scope of claims eligible for external review under the Federal external review process. Specifically, any adverse benefit determination (including a final internal adverse benefit determination) could be reviewed unless it related to a participant's or beneficiary's failure to meet the requirements for eligibility under

the terms of a group health plan (i.e., worker classification and similar issues were not within the scope of the Federal external review process).

Comments received in response to the July 2010 regulations were mixed on the scope of claims eligible for external review. Some commenters argued that PHS Act section 2719 requires the Federal external review process to be "similar to" the NAIC Uniform Model Act and that the broader scope of claims eligible for the Federal external review process is a major departure from the NAIC Uniform Model Act. In addition, some comments from plans and issuers stated that the IROs that are used in the private accredited IRO process traditionally have expertise in adjudicating medical claims, and questioned IROs' experience and expertise with legal and contractual claims. Other comments from IROs and the IRO industry stated that these organizations do currently conduct reviews that involve both medical judgment issues and legal and contractual issues, and that there is sufficient capacity for conducting reviews of such disputes.

Some plan and issuer comments highlighted that, with a limited number of accredited IROs and increased demand for their services, the cost of external review for self-insured group health plans will likely increase. By contrast, an IRO association group commented that member organizations are not at capacity with regard to the volume of work they can perform, and that they are confident that the number of accredited IROs can adequately handle the volume of reviews anticipated for the Federal external review process.

Some plans and issuers stated that handing plan document interpretation and legal interpretation issues over to an IRO may raise issues of consistency of interpretations within a plan, unwarranted consistency across plans that have unique standards, ERISA fiduciary responsibility concerns, and possible conflicts. At the same time, other comments generally

supported the broad scope of claims eligible for the Federal external review process as set forth in the July 2010 regulations. These commenters argued very strongly that it is nearly impossible to adjudicate contractual claims through traditional ERISA enforcement (which generally relies on Federal court adjudication), leaving plan participants and beneficiaries with no effective means of enforcing their rights to benefits under a plan. Consumer organizations further commented that external review finally provides the free, independent means of enforcement to level the playing field of claims adjudication and, therefore, the scope of claims eligible for the Federal external review process should be as broad as possible.

After considering all the comments, with respect to claims for which external review has not been initiated before [insert date 90 days after date of public inspection], the amendment suspends the original rule in the July 2010 regulations regarding the scope of claims eligible for external review for plans using a Federal external review process (regardless of which type of Federal process), temporarily replacing it with a different scope. Specifically, this amendment suspends the broad scope of claims eligible for the Federal external review process and narrows the scope to claims that involve (1) medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment), as determined by the external reviewer; or (2) a rescission of coverage. The more narrow scope under this amendment is more similar to the scope of claims eligible for external review under the NAIC Uniform Model Act. This amendment provides an example describing a plan that generally only provides 30 physical therapy visits but will provide more with an approved treatment plan. The plan's rejection of a treatment plan submitted by a provider for the 31st visit based on a failure to meet the plan's standard for medical necessity involves medical judgment and, therefore, the claim is eligible for external review. Similarly, another example describes a plan that generally does not

provide coverage for services provided on an out-of-network basis, but will provide coverage if the service cannot effectively be provided in network. In this example, again, the plan's rejection of a claim for out-of-network services involves medical judgment. Additional examples of situations in which a claim is considered to involve medical judgment include adverse benefit determinations based on:

- The appropriate health care setting for providing medical care to an individual (such as outpatient versus inpatient care or home care versus rehabilitation facility);
- Whether treatment by a specialist is medically necessary or appropriate (pursuant to the plan's standard for medical necessity or appropriateness);
- Whether treatment involved "emergency care" or "urgent care", affecting coverage or the level of coinsurance;
- A determination that a medical condition is a preexisting condition;
- A plan's general exclusion of an item or service (such as speech therapy), if the plan covers the item or service in certain circumstances based on a medical condition (such as, to aid in the restoration of speech loss or impairment of speech resulting from a medical condition);
- Whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under the plan's wellness program;[32]
- The frequency, method, treatment, or setting for a recommended preventive service, to the extent not specified, in the recommendation or guideline of the U.S. Preventive

[32] See 26 CFR 54.9802-1(f)(2)(iv)(A), 29 CFR 2590.702(f)(2)(iv)(A), and 45 CFR 146.121(f)(2)(iv)(A), requiring that wellness programs that require individuals to satisfy a standard related to a health factor in order to obtain a reward allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is either unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard, or medically inadvisable to attempt to satisfy the otherwise applicable standard.

Services Task Force, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or the Health Resources and Services Administration (as described in PHS Act section 2713 and its implementing regulations);[33] and

- Whether a plan is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act and its implementing regulations, which generally require, among other things, parity in the application of medical management techniques.[34]

The suspension is intended to give the marketplace time to adjust to providing external review. It will also allow the Departments time to evaluate IROs' capacity for handling external reviews; to consider whether current accreditation standards are sufficient to ensure that IROs are capable of making accurate and consistent decisions (both across different plans and across different IROs) regarding legal and contractual issues that do not involve medical judgment or rescissions; and to assess the mechanics of the Federal external review process (and any potential adjustments). The Departments solicit comments on these issues, including on whether limiting the scope of claims during the suspension period will impose administrative costs in determining whether a claim is eligible for external review. The Departments also welcome any data on external review claims actually performed to date under private contracts pursuant to the private accredited IRO process for implementing PHS Act § 2719(b), including number of claims reviewed, type of review (such as whether it involved any medical judgment or not), and costs

[33] See 26 CFR 54.9815-2713T, 29 CFR 2590.715-2713, and 45 CFR 147.130; see also FAQ 8, FAQs About the Affordable Care Act Implementation Part II, regarding the scope, setting, or frequency of the items or services to be covered under the preventive health services recommendations and guidelines (available at http://www.dol.gov/ebsa/faqs/faq-aca2.html and http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs2.html).

[34] See Code section 9812 and 26 CFR 54.9812-1T, ERISA section 712 and 29 CFR 2590.712, and PHS Act section 2726 and 45 CFR 146.136.

associated with the review. The Departments expect that the suspension will be lifted by January 1, 2014, when other consumer protections under the Affordable Care Act take effect. Moreover, if, after taking into account all the relevant information, including public comments, the Departments decide to return to the original rule providing for a broad scope of claims or permanently modify the scope of claims through rulemaking, the Departments will give sufficient advance notice to enable plans, their service providers, IROs, and other affected parties sufficient time to comply with a new rule.

Separate guidance being issued contemporaneous with the publication of this amendment announces standards under which, until January 1, 2014, a State may operate an external review process under Federal standards similar to the process under the NAIC Uniform Model Act (an NAIC-similar process). The Departments are adopting this approach to permit States to operate their external review processes under standards established by the Departments until January 1, 2014, avoiding unnecessary disruption, while States work to adopt the consumer protections set forth in paragraph (c) of the July 2010 regulations. Paragraph (d)(1) of the July 2010 regulations, as amended, will govern the scope of a State external review process under Federal standards similar to the process under the NAIC Uniform Model Act. Because the amended paragraph (d)(1) creates a broader scope of external review than is required under the NAIC Uniform Model Act, and because it would be illogical to require States to make changes to their process to encompass the broader scope of paragraph (d)(1) in their external review process while they work to adopt the consumer protections of the NAIC Uniform Model Act (which has a narrower scope), the Departments are also amending paragraph (d)(1) to permit the Secretaries to modify the scope of the Federal external review process in future guidance to permit State

external review processes (both NAIC-similar processes and NAIC-parallel processes) to the scope that applies under the NAIC Uniform Model Act.

3. Clarification regarding requirement that external review decision be binding

The Departments have received a number of comments on the requirement that an IRO decision be binding on parties. Specifically, the July 2010 regulations provided that an external review decision by an IRO is binding on the plan or issuer, as well as the claimant, except to the extent that other remedies are available under State or Federal law.[35] This binding requirement is also one of the minimum consumer protections set forth in paragraph (c) of the July 2010 regulations.[36]

Some comments received in response to the July 2010 regulations highlighted the importance of this consumer protection and expressed approval that this requirement would minimize delays that could further hurt claimants, as the plan or issuer must provide coverage or payment for the claim immediately upon receipt of a notice of a final external review decision. Other commenters questioned whether the requirement that external review is binding eliminates the plan's or issuer's option to choose to pay a claim at any time during or after the external review process.

Nothing in PHS Act section 2719(b), the July 2010 regulations, or related guidance precludes a plan or issuer from choosing to provide coverage or payment for a benefit. Instead, the Departments read the requirement of the NAIC Uniform Model Act, which is incorporated into the July 2010 regulations, to require plans and issuers to provide a benefit if that is the decision of the IRO. A plan or issuer may not delay payment because the plan disagrees and intends to seek judicial review. Instead, while the plan may be entitled to seek judicial review, it

[35] See 26 CFR 54.9815-2719T(d)(2)(iv), 29 CFR 2590.715-2719(d)(2)(iv), and 45 CFR 147.136(d)(2)(iv).
[36] See 26 CFR 54.9815-2719T(c)(2)(xi), 29 CFR 2590.715-2719(c)(2)(xi), and 45 CFR 147.136(c)(2)(xi).

must act in accordance with the IRO's decision (including by making payment on the claim) unless or until there is a judicial decision otherwise. However, the requirement that the IRO's decision be binding does not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including following a final external review decision that denies the claim or otherwise fails to require such payment or benefits.

After considering all the comments on the requirement that an IRO decision be binding on the plan and issuer, as well as the claimant, this amendment clarifies the language in paragraphs (c)(2)(xi) (regarding the minimum standards for State external review processes) and (d)(2)(iv) (regarding Federal external review process standards). Specifically, these two provisions are amended to add language stating that, for purposes of the binding provision, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise. The Departments welcome comments as to whether any additional clarifications about the binding provision would be helpful.

C. Separate, Contemporaneous Technical Guidance

Separate technical guidance is being issued by the Departments contemporaneous with the publication of this amendment. This technical guidance addresses both State- and Federally-administered external review processes. An appendix to this technical guidance contains revised versions of the three model notices issued by the Departments in connection with the July 2010 regulations. The updated versions of the model notice of adverse benefit determination, model notice of final internal adverse benefit determination, and model notice of final external review decision reflect the requirements contained in the provisions of this amendment and the

guidance. This technical guidance will be available at http://www.dol.gov/ebsa/healthreform and http://cciio.cms.gov.

HHS is issuing also two additional technical guidance documents. The first provides instructions for self-insured nonfederal governmental plans and health insurance issuers with respect to election of a Federal external review process. The second provides, for transparency purposes, updated information on how the county-level estimates pertaining to the 10 percent threshold were calculated for the rules related to culturally and linguistically appropriate notices. Both of these documents will be available at http://cciio.cms.gov.

III. Interim Final Rules

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 amendments promulgated in this rulemaking carry out the provisions of these statutes. Therefore, the foregoing interim final rule authority applies to these amendments.

Under the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*), while a general notice of proposed rulemaking and an opportunity for public comment is generally required before promulgation of regulations, this 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 to issue interim final rules granted by section

9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. Moreover, even if the APA requirements for notice and comment were applicable to this regulation, they have been satisfied. This is because the matters that are the subject of these amendments have already been subjected to public notice and comment, as they were addressed in the July 2010 regulations, and are a logical outgrowth of that document. The amendments made in this interim final rule are being made in response to public comments received on the July 2010 regulations. While the Departments have determined that, even if the APA were applicable, an additional opportunity for public comment is unnecessary in the case of these amendments, the Departments are issuing these amendments as an interim final rule so as to provide the public with an opportunity for public comment on these modifications.

IV. Economic Impact and Paperwork Burden

A. Summary and Need for Regulatory Action--Department of Labor and Department of Health and Human Services

As stated earlier in this preamble, the Departments previously issued the July 2010 regulations implementing PHS Act section 2719, which were published in the **Federal Register** on July 23, 2010 (75 FR 43330). The July 2010 regulations set forth rules with respect to internal claims and appeals and external appeals processes for group health plans and health insurance issuers that are not grandfathered health plans.

As described in detail in Section II of this preamble, after the July 2010 regulations were issued, the Departments received public comments expressing concerns about the burdens associated with several of the regulations' provisions. In response to such comments, the Departments are hereby amending the following provisions of the July 2010 regulations:

- Expedited notification of benefit determinations involving urgent care (paragraph (b)(2)((ii)(B) of the July 2010 regulations);
- Additional notice requirements with respect to notice of adverse benefit determinations or final internal adverse benefit determination (paragraph (b)(2)(ii)(E) of the July 2010 regulations);[37]
- Deemed exhaustion of internal claims and appeals processes (paragraph (b)(2)(ii)(F) of the July 2010 regulations);
- Providing notices in a culturally and linguistically appropriate manner (paragraph (e) of the July 2010 regulations);
- The duration of the transition period for State external review processes (paragraph (c)(3) of the July 2010 regulations); and
- The scope of claims eligible for external review under the Federal external appeals process (paragraph (d)(1) of the July 2010 regulations).

The Departments crafted these amendments to the July 2010 regulations to secure the protections intended by Congress. In accordance with OMB Circular A-4, the Departments have quantified the costs of these amendments where feasible and provided a qualitative discussion of some of the benefits and costs that may stem from them.

The Departments believe that (i) the costs associated with the amended rules are less than the costs associated with the July 2010 regulations, (ii) the amended rules adequately protect the rights of participants, beneficiaries, and policyholders, and (iii) the benefits of the amended rules justify their costs relative to the pre-Affordable Care Act baseline and the July 2010 regulations.

[37] Under the July 2010 regulations, this included the date of service, the health care provider, and the claim amount (if applicable), as well as the diagnosis code (such as an ICD-9 code, ICD-10 code, or DSM-IV code), the treatment code (such as a CPT code) , and the corresponding meanings of these codes.

B. Executive Orders 12866 and 13563--Department of Labor and Department of Health and Human Services

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Departments provide an assessment of the potential costs and benefits associated with each amended regulatory provision below, as summarized in Table 1.

TABLE. 1--*Accounting Table*

Benefits				
Qualitative: Amendments to the interim final regulations ensure urgent care benefit determinations are made in a timely manner, increase patient privacy, ensure non-English speakers understand their rights, and provide that claimants will be deemed to have exhausted their administrative proceedings and can proceed to court or external review if a plan or issuer fails to strictly adhere to the regulatory requirements with the exception of the requirements that are described in the amendment. These amendments are expected to reduce compliance costs while still ensuring patient protections.				
Costs	**Estimate**	**Year Dollar**	**Discount Rate**	**Period Covered**
Annualized Monetized ($millions/year)	1.7	2011	7%	2012-2014
	1.7	2011	3%	2012-2014
Qualitative: Monetized costs are for providing notices upon request in a culturally and linguistically appropriate manner. Non-monetized costs include costs for plans and issuers to respond to requests for diagnostic and treatment codes, and costs incurred by claimants to resolve whether a plan or insurer's failure to strictly adhere to the regulatory requirements is sufficient for a claimant to proceed directly to an external or court review.				

1. Estimated Number of Affected Entities

For purposes of estimating the entities affected by these amendments to the July 2010 regulations, the Departments have defined a large group health plan as an employer plan with 100 or more workers and a small group plan as an employer plan with fewer than 100 workers.

The Departments make the following estimates about plans and issuers affected by these amendments: (1) there are approximately 72,000 large and 2.8 million small ERISA-covered group health plans with an estimated 97.0 million participants in large group plans and 40.9 million participants in small group plans;[38] (2) there are 126,000 governmental plans with 36.1 million participants in large plans and 2.3 million participants in small plans;[39] and (3) there are 16.7 million individuals under age 65 covered by individual health insurance policies.[40]

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

2. Benefits and Costs

The benefits and costs of the amendments to the July 2010 regulations are discussed together under this section, because the primary effect of the amendments is to reduce the cost of compliance.

a. Expedited notification of benefit determination involving urgent care. As discussed in detail above, the July 2010 regulations generally provide that a plan or issuer must notify a claimant of a benefit determination with respect to an urgent care claim as soon as possible taking into account the medical exigencies, but no later than 24 hours after the receipt of the claim by the plan or issuer. This was a change from the DOL claims procedure regulation,

[38] All participant counts and the estimates of individual policies are from the 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.
[39] Estimate is from the 2007 Census of Government.
[40] US Census Bureau, Current Population Survey, March 2009.

which requires an urgent care determination to be made not later than 72 hours after receipt of the claim by a group health plan. The Departments received several comments regarding the burdens associated with meeting the 24-hour turnaround. Some commenters argued that some of the claims constituting "urgent care" and thus qualifying for the expedited timeframe really do not need to be decided within 24 hours. Moreover, a number of commenters highlighted that the 72-hour provision was never anything more than a "backstop"; the general rule under both the July 2010 regulations and the DOL claims procedure regulation is for a decision as soon as possible consistent with the medical exigencies involved, making the change to a 24-hour timeframe unnecessary for the most serious medical cases. Finally, some commenters cited the Emergency Medical Treatment and Labor Act (EMTALA)[41], which generally requires emergency room care to be treated with or without insurance or preauthorization and, therefore, mitigates much of the need for expedited pre-service emergency claims determinations in many situations.

After considering the comments, and the costs and benefits of an absolute 24-hour decision-making deadline, the amendment permits plans and issuers to follow the original rule in the DOL claims procedure regulation (requiring decision-making in the context of pre-service urgent care claims as soon as possible consistent with the medical exigencies involved but in no event no later than 72 hours), provided the plan or issuer defers to the attending provider with respect to the decision as to whether a claim constitutes "urgent care."

The Departments expect that this amendment will ensure urgent care benefit determinations are made in a timely manner while reducing burden on plans and issuers for several reasons. ERISA-covered plans were already subject to this requirement; therefore, there is no additional burden imposed on such plans from the pre-Affordable Care Act baseline. For

[41] 42 U.S.C. §1395dd.

self-insured nonfederal governmental plans and issuers in the individual market, the 72-hour requirement would increase burden from a pre-Affordable Care Act baseline to the extent that such plans and issuers are not already meeting this standard. The Departments do not have sufficient data to estimate the fraction of plans and issuers that were not already in compliance with this standard. Many claims filed with self-insured nonfederal governmental plans and individual market issuers already could have been meeting this requirement for urgent care claims, because ERISA claims constitute a large portion of health claims, and the Departments understand that, in general, issuers and service providers apply the same claims and appeals standards to ERISA-covered and non-ERISA-covered plans.

Plans and issuers that previously were not subject to the DOL claims procedure regulation and that are not already meeting the claims and appeals standard under the DOL claims procedure regulation, could incur additional costs to become compliant with the 72-hour standard, but the Departments expect these costs to be less than those associated with a 24-hour standard. Speeding up the notification process for these determinations to meet the 72-hour standard could necessitate incurring additional cost to add more employees or find other ways to shorten the timeframe, but again such costs are expected to be less than the costs associated with meeting the 24-hour standard provided in the July 2010 regulations. Additional costs for claimants may be associated with this requirement if meeting the 72-hour timeframe results in more claims being denied than would have been denied under a longer notification period, but again such costs are expected to be less than the costs associated with meeting the 24-hour standard provided in the July 2010 regulations. The Departments do not have sufficient data to estimate such costs.

b. Additional notice requirements for internal claims and appeals. As discussed above, the July 2010 regulations had additional content requirements for the required notices. The Departments received comments addressing the requirements to include the diagnosis code (such as an ICD-9 code, ICD-10 code, or DSM-IV code), the treatment code (such as a CPT code), and the corresponding meanings of these codes. Concerns were raised about patient privacy, interference with the doctor-patient relationship, and high costs. Commenters also pointed out that there are currently over 20,000 treatment and diagnosis codes in use today, presenting a costly administrative and operational challenge for plans and issuers. Comments also questioned the efficacy of providing codes which some argued are often very difficult for the average patient to understand.

After considering all the comments, and the costs and benefits of the additional disclosure, the amendment to the July 2010 regulations eliminates the requirement to automatically provide the diagnosis and treatment codes as part of a notice of adverse benefit determination (or final internal adverse benefit determination) and instead requires plans and issuers to provide notification of the opportunity to request the diagnosis and treatment codes (and their meanings) in all notices of adverse benefit determination (and notices of final internal adverse benefit determination) and to provide this information upon request.

Making the codes only available upon request protects patients' privacy while reducing the burden for plans and issuers to redesign notices. However, plans and issuers will still incur costs to establish procedures to receive, process, and mail the requests. The Departments do not have a basis to estimate the net cost associated with this amendment, because they do not have sufficient data available to estimate the savings that will result from plans and issuers not needing to redesign notices or calculate the number of future requests.

c. Deemed exhaustion of internal claims and appeals process. The July 2010 regulations provide that claimants can immediately seek judicial or external review if a plan or issuer failed to "strictly adhere" to all of the July 2010 regulations' requirements for internal claims and appeals processes, regardless of whether the plan or issuer asserted that it "substantially complied" with the July 2010 regulations. This approach received a number of negative comments from some issuers and plan sponsors, who prefer a "substantial compliance" approach, especially in cases where deviations from the regulatory standards were minor.

In response to these comments, the Departments are retaining the approach to this requirement, but this amendment also adds a new paragraph (b)(2)(ii)(F)(2) to the July 2010 regulations to provide an exception to the strict compliance standard for errors that are minor and meet certain other specified conditions. The new paragraph will also protect claimants whose attempts to pursue other remedies under paragraph (b)(2)(ii)(F)(1) of the interim final regulations are rejected by a reviewing tribunal. Under the amended approach, any violation of the procedural rules of July 2010 regulations pertaining to internal claims and appeals would permit a claimant to seek immediate external review or court action, as applicable, unless the violation was:

(1) De minimis;

(2) Non-prejudicial;

(3) Attributable to good cause or matters beyond the plan's or issuer's control;

(4) In the context of an ongoing good-faith exchange of information; and

(5) Not reflective of a pattern or practice of non-compliance.[42]

[42] In addition, the claimant would be entitled, upon written request, to an explanation of the plan's or issuer's basis for asserting that it meets this standard, so that the claimant could make an informed judgment about whether to seek immediate review. Finally, if the external reviewer or the court rejects the claimant's request for immediate review

The Departments expect that this amendment will protect patients' right to proceed to external review while lowering costs based on the assumption that internal appeals are less expensive than external reviews or litigation. However, the amendment may add some costs, because participants and policyholders now may face uncertainty regarding whether a particular violation is minor. Many claimants may incur a cost to seek professional advice, because they will not be able to make this judgment on their own behalf. Alternatively, some claimants might seek immediate external review or judicial review and be denied it. The Departments do not have a sufficient basis to estimate these costs.

d. Culturally and Linguistically Appropriate Notices. PHS Act section 2719 requires group health plans and health insurance issuers to provide relevant notices in a culturally and linguistically appropriate manner. The July 2010 regulations set forth a requirement to provide notices in a non-English language based on separate thresholds of the number of people who are literate in the same non-English language. In the group market, the threshold set forth in the July 2010 regulations differs depending on the number of participants in the plan as follows:

- For a plan that covers fewer than 100 participants at the beginning of a plan year, the threshold is 25 percent of all plan participants being literate only in the same non-English language.
- For a plan that covers 100 or more participants at the beginning of a plan year, the threshold is the lesser of 500 participants, or 10 percent of all plan participants, being literate only in the same non-English language.[43]

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on the basis that the plan met this standard, this amendment would give the claimant the right to resubmit and pursue the internal appeal of the claim.

[43] These thresholds were adapted from the DOL regulations regarding style and format for a summary plan description, at 29 CFR 2520.102-2(c) for participants who are not literate in English.

For the individual market, the threshold is 10 percent of the population residing in the county being literate only in the same non-English language.[44]

Under the July 2010 regulations, if an applicable threshold is met with respect to a non-English language, the plan or issuer must provide the notice upon request in the non-English language. Additionally, the plan or issuer must include a statement in the English versions of all notices, prominently displayed in the non-English language, offering the provision of such notices in the non-English language. Finally, to the extent the plan or issuer maintains a customer assistance process (such as a telephone hotline) that answers questions or provides assistance with filing claims and appeals, the plan or issuer must provide such assistance in the non-English language.

As discussed earlier in this preamble, the Departments received comments that raised concerns regarding the burdens imposed by this provision. In response to these comments, the Departments have decided to amend the July 2010 regulations' provisions related to the provision of notices in a culturally and linguistically appropriate manner to establish a single threshold with respect to the number of people who are literate only in the same non-English language for both the group and individual markets. Under the amended provision, for group health plans and health insurance issuers offering group or individual health insurance coverage, the threshold percentage of people who are literate only in the same non-English language will be set at 10 percent or more of the population residing in the claimant's county, as determined based on American Community Survey (ACS) data published by the United States Census Bureau. Table 2, below provides a chart listing those 255 U.S. counties (78/255 are in Puerto Rico) in which at least 10 percent of the population speak a particular non-English language and

[44] The individual market threshold was generally adapted from the approach used under the Medicare Advantage program, which required translation of materials in languages spoken by more than 10 percent of the general population in a service area at the time the threshold was established.

speak English less than "very well." These data are applicable for 2011 and are calculated using 2005-2009 ACS data. The Departments will update this guidance annually on their website if there are changes to the list of the counties determined to meet this 10 percent threshold for the county's population being literate only in the same non-English language.

TABLE 2.--*Percent of the County Population that Speak a Particular Non-English Language and Speak English Less Than "Very Well", by U.S. County*[45]

		NON-ENGLISH LANGUAGE			
STATE	COUNTY	Spanish %	Chinese %	Tagalog %	Navajo %
AK	Aleutians West Census Area	13		16	
AK	Aleutians East Borough			35	
AR	Sevier County	17			
AZ	Apache County				12
AZ	Maricopa County	11			
AZ	Yuma County	22			
AZ	Santa Cruz County	39			
CA	Colusa County	27			
CA	Fresno County	15			
CA	Glenn County	14			
CA	Imperial County	32			
CA	Kern County	16			
CA	Kings County	18			
CA	Los Angeles County	19			
CA	Madera County	18			
CA	Merced County	20			
CA	Monterey County	25			
CA	Napa County	14			
CA	Orange County	14			
CA	Riverside County	15			
CA	San Benito County	21			
CA	San Bernardino County	15			
CA	San Diego County	11			
CA	San Francisco County		12		
CA	San Joaquin County	12			
CA	Santa Barbara County	15			

[45] Data are from the 2005-2009 ACS available at www.census.gov/acs . Only those counties where at least 10% of the county speak a particular non-English language and speak English less than "very well" are listed.

CA	Santa Cruz County	12			
CA	Stanislaus County	13			
CA	Sutter County	12			
CA	Tulare County	21			
CA	Ventura County	14			
CO	Adams County	12			
CO	Costilla County	11			
CO	Denver County	12			
CO	Eagle County	16			
CO	Garfield County	12			
CO	Lake County	11			
CO	Phillips County	12			
CO	Prowers County	12			
CO	Saguache County	15			
CO	Yuma County	10			
FL	Collier County	13			
FL	DeSoto County	21			
FL	Glades County	10			
FL	Hardee County	22			
FL	Hendry County	26			
FL	Miami-Dade County	31			
FL	Okeechobee County	12			
FL	Osceola County	16			
GA	Atkinson County	12			
GA	Echols County	20			
GA	Hall County	16			
GA	Telfair County	10			
GA	Whitfield County	18			
IA	Buena Vista County	12			
ID	Clark County	22			
ID	Minidoka County	11			
ID	Owyhee County	12			
ID	Power County	13			
IL	Kane County	15			
KS	Finney County	16			
KS	Ford County	23			
KS	Grant County	16			
KS	Hamilton County	11			
KS	Seward County	26			
KS	Stanton County	19			
KS	Stevens County	11			
KS	Wichita County	12			
KS	Wyandotte County	10			
NC	Alleghany County	14			

NC	Duplin County	14			
NE	Colfax County	23			
NE	Dakota County	14			
NE	Dawson County	15			
NJ	Hudson County	18			
NJ	Passaic County	16			
NJ	Union County	13			
NM	Chaves County	11			
NM	Dona Ana County	18			
NM	Hidalgo County	12			
NM	Lea County	11			
NM	Luna County	18			
NM	McKinley County				15
NM	Mora County	11			
NM	Santa Fe County	12			
NM	Chaves County	11			
NV	Clark County,	11			
NY	Bronx County	20			
NY	New York County	10			
NY	Queens County	12			
OK	Texas County	18			
OR	Hood River County	15			
OR	Marion County	11			
OR	Morrow County	14			
TX	Andrews County	11			
TX	Atascosa County	11			
TX	Bailey County	18			
TX	Bexar County	12			
TX	Brooks County	18			
TX	Calhoun County	12			
TX	Cameron County	30			
TX	Camp County	11			
TX	Castro County	20			
TX	Cochran County	18			
TX	Concho County	29			
TX	Crane County	10			
TX	Crockett County	20			
TX	Crosby County	11			
TX	Culberson County	15			
TX	Dallam County	12			
TX	Dallas County	18			
TX	Dawson County	12			
TX	Deaf Smith County	20			
TX	Dimmit County	33			

TX	Duval County	26			
TX	Ector County	12			
TX	Edwards County	10			
TX	El Paso County	29			
TX	Frio County	16			
TX	Garza County	35			
TX	Gonzales County	14			
TX	Hale County	12			
TX	Hall County	14			
TX	Hansford County	16			
TX	Harris County	18			
TX	Hidalgo County	35			
TX	Howard County	16			
TX	Hudspeth County	31			
TX	Jim Hogg County	26			
TX	Jim Wells County	13			
TX	Karnes County	17			
TX	Kenedy County	14			
TX	Kinney County	15			
TX	Kleberg County	11			
TX	La Salle County	22			
TX	Lamb County	15			
TX	Lipscomb County	14			
TX	Lynn County	12			
TX	Maverick County	48			
TX	Midland County	11			
TX	Moore County	19			
TX	Nueces County	12			
TX	Ochiltree County	17			
TX	Parmer County	22			
TX	Pecos County	18			
TX	Presidio County	36			
TX	Reagan County	21			
TX	Reeves County	27			
TX	San Patricio County	12			
TX	Schleicher County	12			
TX	Sherman County	14			
TX	Starr County	43			
TX	Sterling County	11			
TX	Sutton County	18			
TX	Tarrant County	10			
TX	Terrell County	12			
TX	Terry County	11			
TX	Titus County	20			

TX	Travis County	12			
TX	Upton County	11			
TX	Uvalde County	15			
TX	Val Verde County	29			
TX	Ward County	12			
TX	Webb County	49			
TX	Willacy County	20			
TX	Winkler County	13			
TX	Yoakum County	23			
TX	Zapata County	36			
TX	Zavala County	33			
UT	San Juan County				12
VA	Manassas city	17			
VA	Manassas Park city	18			
WA	Adams County	23			
WA	Douglas County	11			
WA	Franklin County	27			
WA	Grant County	16			
WA	Yakima County	17			
PR	Anasco Municipio	85			
PR	Adjuntas Municipio	86			
PR	Aguada Municipio	81			
PR	Aguadilla Municipio	78			
PR	Aguas Buenas Municipio	90			
PR	Aibonito Municipio	82			
PR	Arecibo Municipio	83			
PR	Arroyo Municipio	84			
PR	Barceloneta Municipio	78			
PR	Barranquitas Municipio	87			
PR	Bayamon Municipio	78			
PR	Cabo Rojo Municipio	82			
PR	Caguas Municipio	80			
PR	Camuy Municipio	88			
PR	Canovanas Municipio	83			
PR	Carolina Municipio	77			
PR	Catano Municipio	82			
PR	Cayey Municipio	86			
PR	Ceiba Municipio	73			
PR	Ciales Municipio	88			
PR	Cidra Municipio	86			
PR	Coamo Municipio	84			
PR	Comero Municipio	93			
PR	Corozal Municipio	88			
PR	Culebra Municipio	76			

PR	Dorado Municipio	77			
PR	Fajardo Municipio	78			
PR	Florida Municipio	81			
PR	Guayama Municipio	80			
PR	Guayanilla Municipio	85			
PR	Guaynabo Municipio	69			
PR	Gurabo Municipio	81			
PR	Gußnica Municipio	83			
PR	Hatillo Municipio	86			
PR	Hormigueros Municipio	74			
PR	Humacao Municipio	83			
PR	Isabela Municipio	85			
PR	Jayuya Municipio	91			
PR	Juana Diaz Municipio	86			
PR	Juncos Municipio	85			
PR	Lajas Municipio	83			
PR	Lares Municipio	87			
PR	Las Marias Municipio	91			
PR	Las Piedras Municipio	85			
PR	Loiza Municipio	89			
PR	Luquillo Municipio	79			
PR	Manati Municipio	84			
PR	Maricao Municipio	95			
PR	Maunabo Municipio	88			
PR	Mayaguez Municipio	77			
PR	Moca Municipio	86			
PR	Morovis Municipio	87			
PR	Naguabo Municipio	83			
PR	Naranjito Municipio	91			
PR	Orocovis Municipio	91			
PR	Patillas Municipio	84			
PR	Penuelas Municipio	86			
PR	Ponce Municipio	80			
PR	Quebradillas Municipio	83			
PR	Rincon Municipio	73			
PR	Rio Grande Municipio	85			
PR	Sabana Grande Municipio	83			
PR	Salinas Municipio	86			
PR	San German Municipio	85			
PR	San Juan Municipio	73			
PR	San Lorenzo Municipio	83			
PR	San Sebastian Municipio	84			
PR	Santa Isabel Municipio	86			
PR	Toa Alta Municipio	80			

PR	Toa Baja Municipio	80			
PR	Trujillo Alto Municipio	79			
PR	Utuado Municipio	83			
PR	Vega Alta Municipio	83			
PR	Vega Baja Municipio	76			
PR	Vieques Municipio	83			
PR	Villalba Municipio	88			
PR	Yabucoa Municipio	86			
PR	Yauco Municipio	85			

These amendments also require each notice sent by a plan or issuer to an address in a county that meets this threshold to include a one-sentence statement in the relevant non-English language about the availability of language services to be provided by the Departments. The Departments have provided guidance with sample sentences in the relevant languages in separate guidance being issued contemporaneous with the publication of this amendment.

In addition to including a statement in all notices in the relevant non-English language, a plan or issuer would be required to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request.

The Departments expect that the largest cost associated with the amended rules for culturally and linguistically appropriate notices will be for plans and issuers to provide notices in the applicable non-English language upon request. Based on the ACS data, the Departments estimate that there are about 12 million individuals living in covered counties that are literate in a non-English Language. The ACS did not start collecting insurance coverage information until 2008. Therefore, to estimate the percentage of the 12 million affected individuals that were insured, the Departments used the percentage of the population in the State that reported being insured by private or public employer insurance or in the individual market from the 2009

Current Population Survey (CPS). [46] This results in an estimate of approximately seven million individuals who are eligible to request translation services.

In discussions with the regulated community, the Departments found that experience in California, which has a State law requirement for providing translation services, indicates that requests for translations of written documents averages 0.098 requests per 1,000 members. While the California law is not identical to the amendment to the July 2010 regulations, and the demographics for California do not match other counties, for purposes of this analysis, the Departments used this percentage to estimate of the number of translation service requests that plan and issuers can expect to receive. Industry experts also told the Departments that while the cost of translation services varies, $500 per document is a reasonable approximation of translation cost.

Using the ACS and the CPS, the Departments estimate 34 million insured lives in the affected counties. Based on the foregoing, the Departments estimate that the cost to provide translation services will be approximately $1.7 million annually (34,087,000 lives * 0.098/1000 * $500).

e. Duration of the transition period for State external review processes. These amendments to the July 2010 regulations modify the transition period under paragraph (c)(3) so that the last day of the transition period is December 31, 2011. Modifying the transition period gives states additional time to implement State external review processes that conform to paragraph (c)(2). This modification produces benefits and costs to participants and beneficiaries depending upon which state they live in and the timing of the beginning of the plan year. HHS is working closely with states to help them have external review processes that meet the

[46] Please note that using state estimates of insurance coverage could lead to an over estimate if those reporting in the ACS survey that they speak English less than "very well" are less likely to be insured than the state average.

requirements of paragraph (c)(2). The July 2010 regulations would have participants living in states with laws that do not meet the minimum consumer protections in paragraph (c)(2) entering the Federal external review process that would provide more consumer protections. However, this requirement to enter the Federal external review process would take effect upon the start of a new plan year beginning on or after July 1, 2011.

This modification delays coverage of external review for participants whose plan year would have started between July 1, 2011 and December 31, 2011, but provides coverage sooner for participants in plans with plan years beginning after January 1, 2012, and has no change for participants in plans with plan years beginning on January 1, 2012.

The annual reporting form for certain ERISA covered health plans, the Form 5500, has information on health plan year end dates and also the number of participants in health plans. While most health plans with less than 100 participants are not required to file the Form 5500, the Departments are able to observe the plan year end dates and hence the plan year start dates for large plans. The Departments looked at the dispersion of plan year start dates for plans that filed the Form 5500 and found that nearly 76 percent of participants are in plans with a plan year start date of January 1, 2012 and hence will not be effected by the change in the rule; nearly 13 percent of participants are in plans that could possibly see a delay in receiving the protections of external review, while just over 10 percent of participants will be able to access the protections sooner. These estimates did not take into account the state in which the plan was located. The Departments do not have data on the start date of policies in the individual market. While on net about 2.4 percent of participants in affected plans could see a delay in receiving the protections, these costs are offset by giving states, and issuers additional time, and hence lower costs, to prepare for complying with the rule.

f. Scope of Federal External Review. Paragraph (d)(1) of the July 2010 regulations provides that any adverse benefit determination (including a final internal adverse benefit determination) could be brought to the Federal external review process unless it related to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan (i.e., worker classification and similar issues were not within the scope of the Federal external review process). As discussed earlier in this preamble, comments received in response to the July 2010 regulations indicate that the scope of external review claims was too broad.

After considering all the comments, with respect to plans subject to the Federal external review process, for claims for which external review has not been initiated before **[insert date 90 days after date of public inspection]**, the amendment suspends the original rule in the July 2010 regulations regarding the scope of claims eligible for external review for plans using the Federal process, temporarily replacing it with a different scope. Specifically, this amendment suspends the broad scope of claims eligible for external review and narrows the scope to those that involve (1) medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment), as determined by the external reviewer; or (2) a rescission of coverage. The suspension is intended to give the marketplace time to adjust to providing external review. The Departments believe that, once the market has so adjusted, it will become clear that the benefits of the July 2010 regulations' broader scope would be likely to justify its costs.

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 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.

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 APA (5 U.S.C. chapter 5) does not apply to these temporary 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

1. Department of Labor and Department of the Treasury

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. Department of Labor and Department of the Treasury: Affordable Care Act Internal Claims and Appeals and External Review Disclosures for Non-Grandfathered Plans

These amendments make two changes to the interim final regulations that affect the paperwork burden. The first is an amendment no longer requiring that diagnosis and treatment codes be included on notices of adverse benefit determination and final internal adverse benefit determination. Instead, they must notify claimants of the opportunity to receive the codes on request and plans and issuers must provide the codes upon request. The Departments expect that this change will lower costs, because plans and issuers no longer will have to provide the codes on the notices. Plans and issuers will incur a cost to establish procedures for receive, process, and mail the codes upon request; however, the Departments are unable to estimate such cost due to a lack of a basis for an estimate of the number of requests that will be made for the codes.

The amendments also change the method for determining who is eligible to receive a notice in a culturally and linguistically appropriate manner, and the information that must be provided to such persons. The previous rule was based on the number of employees at a firm. The new rule is based on whether a participant or beneficiary resides in a county where ten percent or more of the population residing in the county is literate only in the same non-English language.

Participants and beneficiaries residing in an affected county and speaking an applicable non-English language will now receive a one-sentence statement in all notices written in the applicable non-English language about the availability of language services. In addition to including the statement, plan and issuers are required to provide a customer assistance process

(such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon requests.

The Departments understand that oral translation services are already provided for nearly all covered participants and beneficiaries. Therefore, no additional burden is associated with this requirement of the amendment. The Departments estimate that plans will incur an annual cost burden of $1.2 million to translate written notices into the relevant non-English language.[47]

Based on the foregoing, the Departments have adjusted the total estimated cost burden for this information collection. The cost burden is $243,000 in 2011, $1.7 million in 2012, and $1.8 million in 2013.

Type of Review: Revised collection.

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

Title: Affordable Care Act Internal Claims and Appeals and External Review Disclosures for Non-Grandfathered Plans

OMB Number: 1210–0144; 1545–2182.

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

Total Respondents: 1,020,000 (three-year average).

Total Responses: 111,000(three-year average).

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 233 hours (Employee Benefits Security Administration); 233 hours (Internal Revenue Service) (three-year average).

[47] The Department's methodology for this estimate is explained in IV, B, 2, d, above.

Estimated Total Annual Burden Cost: $628,900 (Employee Benefits Security Administration); $628,900 (Internal Revenue Service) (three-year average).

2. Department of Health and Human Services

a. ICR Regarding Affordable Care Act Internal Claims and Appeals and External Review Disclosures for Non-grandfathered Plans

As discussed above in the Department of Labor and Department of the Treasury PRA section, these amendments make two changes to the interim final regulations that affect the paperwork burden. The first is an amendment no longer requiring that diagnosis and treatment codes be included on notices of adverse benefit determination and final internal adverse benefit determination. Instead these codes are available upon request. The Departments expect that this change will lower costs compared to the July 2010 regulations because plans and issuers no longer will have to provide the codes on the notices. Plans and issuers will incur a cost to establish procedures for receiving, processing, and mailing the codes upon request; however, the Departments are unable to estimate such cost due to lack of a basis for an estimate of the number of requests that will be made for the codes. Second, the amendments also changes who is eligible to receive a notice in a culturally or linguistically appropriate manner.

The Departments estimated the new cost burden of providing the translation of requested notices into the applicable non-English language. The annual cost burden is estimated to be $430,000 annually starting in 2012. The derivation of this estimate was discussed above in the Economic Impact section.

Due to the amendments, the Department has adjusted the total estimated costs of this information collection. The Department estimates that State and local governmental plans and issuers offering coverage in the individual market will incur a total hour burden of 570,804 hours in 2011, 998,807 hours in 2012, and 1.22 million hours in 2013 to comply with equivalent costs

of $28.2 million in 2011, $57.4 million in 2012, and $70.5 million in 2013. The total cost burden for those plans that use service providers, including the cost of mailing all responses is estimated to be $20.7 million in 2011, $37.9 million in 2012, and $51.7 million in 2013.

The hour and cost burden is summarized below:

Type of Review: Revised collection.

Agency: Department of Health and Human Services.

Title: Affordable Care Act Internal Claims and Appeals and External Review Disclosures

OMB Number: 0938–1099.

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

Respondents: 46,773 (three-year average).

Responses: 218,650,000 (three-year average).

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 929,870 hours (three-year average).

Estimated Total Annual Burden Cost: $36,600,000 (three-year average).

We have requested emergency OMB review and approval of the aforementioned information collection requirements by July 1, 2011. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage or email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786–1326.

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, CMS-9993-IFC2

Fax: (202) 395 6974; or

Email: OIRA_submission@omb.eop.gov

F. Congressional Review Act

These amendments to the 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.

G. 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 amendments to the 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.

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 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 amendments to the 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 to implement an internal and external appeals process that will meet or exceed 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. Furthermore, the Departments have opined that, in the instance of a group health plan providing coverage through group health insurance, the issuer will be required to follow the external review procedures established in State law (assuming the State external review procedure meets the minimum standards set out in these interim final rules).

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 (NAIC), meeting with NAIC staff counsel on issues arising from the interim final regulations 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, including the provisions of section 2719 of the PHS Act.

Throughout the process of developing these amendments to the 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 regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare and Medicaid Services 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 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.

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.

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

Approved: June 21, 2011

Emily S. McMahon
Acting Assistant Secretary of the Treasury (Tax Policy).

Signed this _____20th____ day of _____June_____, 2011.

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

CMS-9993-IFC2

Approved: June 16, 2011

Donald Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: June 17, 2011

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 general authority citation for part 54 continues to read as follows:

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

Par. 2. Section 54.9815-2719T is amended by:

1. Revising paragraphs (b)(2)(ii)(B), (b)(2)(ii)(E)(1), (b)(2)(ii)(F), (c)(2)(xi), (c)(3), (d)(1), (d)(2)(iv) and (e).

2. Redesignating (b)(2)(ii)(E)(2), (b)(2)(ii)(E)(3), and (b)(2)(ii)(E)(4) as (b)(2)(ii)(E)(3), (b)(2)(ii)(E)(4), and (b)(2)(ii)(E)(5), respectively.

3. Adding new paragraph (b)(2)(ii)(E)(2).

The revisions and addition read as follows:

§54.9815-2719T Internal claims and appeals and external review processes (temporary).

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Expedited notification of benefit determinations involving urgent care. The requirements of 29 CFR 2560.503-1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours

after receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503-1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

* * * * *

(E) * * *

(1) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

* * * * *

(F) Deemed exhaustion of internal claims and appeals processes – (1) In the case of a plan or issuer that fails to adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(2) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable.

The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(2) Notwithstanding paragraph (b)(2)(ii)(F)(1) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(1) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(2), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity

to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

* * * * *

(c) * * *

(2) * * *

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

* * * * *

(3) Transition period for external review processes. (i) Through December 31, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2011, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) For final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2012, the Federal external review process will apply unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section.

(d) * * *

(1) Scope – (i) In general. Subject to the suspension provision in paragraph (d)(1)(ii) of this section and except to the extent provided otherwise by the Secretary in guidance, the Federal external review process established pursuant to this paragraph (d) applies to any adverse benefit determination or final internal adverse benefit determination (as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section), except that a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the Federal external review process under this paragraph (d).

(ii) Suspension of general rule. Unless or until this suspension is revoked in guidance by the Secretary, with respect to claims for which external review has not been initiated before **[insert date 90 days after date of public inspection]**, the Federal external review process established pursuant to this paragraph (d) applies only to:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(iii) Examples. This rules of paragraph (d)(1)(ii) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual A seeks coverage for a 31st physical therapy visit. A's health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, A receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) Conclusion. In this Example 1, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) Facts. A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual B seeks coverage for a specialized medical procedure from an out-of-network provider because B believes that the procedure cannot be effectively provided in network. B receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) Conclusion. In this Example 2, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

* * * * *

(2) * * *

(iv) These standards will provide that an external review decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide any benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

* * * * *

(e) Form and manner of notice – (1) In general. For purposes of this section, a group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) Requirements – (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

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

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

* * * * *

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:

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 2590.715-2719 is amended by:

1. Revising paragraphs (b)(2)(ii)(B), (b)(2)(ii)(E)(1), (b)(2)(ii)(F), (c)(2)(xi), (c)(3), (d)(1), (d)(2)(iv), and (e).

2. Redesignating (b)(2)(ii)(E)(2), (b)(2)(ii)(E)(3), and (b)(2)(ii)(E)(4) as (b)(2)(ii)(E)(3), (b)(2)(ii)(E)(4), and (b)(2)(ii)(E)(5), respectively.

3. Adding new paragraph (b)(2)(ii)(E)(2).

The revisions and addition read as follows:

§2590.715-2719 Internal claims and appeals and external review processes.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Expedited notification of benefit determinations involving urgent care. The requirements of 29 CFR 2560.503-1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503-1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

* * * * *

(E) * * *

(1) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

* * * * *

(F) Deemed exhaustion of internal claims and appeals processes – (1) In the case of a plan or issuer that fails to adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(2) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(2) Notwithstanding paragraph (b)(2)(ii)(F)(1) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(1) of this section on the

basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(2), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

* * * * *

(c) * * *

(2) * * *

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

* * * * *

(3) Transition period for external review processes. (i) Through December 31, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2011, an applicable State external review process will be considered binding on

the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) For final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2012, the Federal external review process will apply unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section.

(d) * * *

(1) Scope – (i) In general. Subject to the suspension provision in paragraph (d)(1)(ii) of this section and except to the extent provided otherwise by the Secretary in guidance, the Federal external review process established pursuant to this paragraph (d) applies to any adverse benefit determination or final internal adverse benefit determination (as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section), except that a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the Federal external review process under this paragraph (d).

(ii) Suspension of general rule. Unless or until this suspension is revoked in guidance by the Secretary, with respect to claims for which external review has not been initiated before the effective date of this paragraph (d)(1) (**[insert date 90 days after date of public inspection]**), the Federal external review process established pursuant to this paragraph (d) applies only to:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to,

those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(iii) Examples. This rules of paragraph (d)(1)(ii) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual A seeks coverage for a 31st physical therapy visit. A's health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, A receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) Conclusion. In this Example 1, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) Facts. A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual B seeks coverage for a specialized medical procedure from an out-of-network provider because B believes that the procedure cannot be effectively provided in network. B receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) Conclusion. In this Example 2, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot

effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

* * * * *

(2) * * *

(iv) These standards will provide that an external review decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide any benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

* * * * *

(e) Form and manner of notice – (1) In general. For purposes of this section, a group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) Requirements – (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-

English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 147 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: Sections 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.

2. Section 147.136 is amended by:

1. Revising paragraphs (b)(2)(ii)(B), (b)(2)(ii)(E)(1), (b)(2)(ii)(F), (c)(2)(xi), (c)(3), (d)(1), (d)(2)(iv), and (e).

2. Redesignating (b)(2)(ii)(E)(2), (b)(2)(ii)(E)(3), and (b)(2)(ii)(E)(4) as (b)(2)(ii)(E)(3), (b)(2)(ii)(E)(4), and (b)(2)(ii)(E)(5), respectively.

3. Adding new paragraph (b)(2)(ii)(E)(2).

The revisions and addition read as follows:

§ 147.136 Internal claims and appeals and external review processes.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Expedited notification of benefit determinations involving urgent care. The requirements of 29 CFR 2560.503-1(f)(2)(i) (which generally provide, among other things, in the

case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503-1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

* * * * *

(E) * * *

(1) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

* * * * *

(F) Deemed exhaustion of internal claims and appeals processes – (1) In the case of a plan or issuer that fails to adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this

paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(2) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(2) Notwithstanding paragraph (b)(2)(ii)(F)(1) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(1) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(2), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate

review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

* * * * *

(c) * * *

(2) * * *

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

* * * * *

(3) Transition period for external review processes. (i) Through December 31, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2011, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) For final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2012, the Federal external review process will apply unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section.

(d) * * *

(1) Scope – (i) In general. Subject to the suspension provision in paragraph (d)(1)(ii) of this section and except to the extent provided otherwise by the Secretary in guidance, the Federal external review process established pursuant to this paragraph (d) applies to any adverse benefit determination or final internal adverse benefit determination (as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section), except that a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the Federal external review process under this paragraph (d).

(ii) Suspension of general rule. Unless or until this suspension is revoked in guidance by the Secretary, with respect to claims for which external review has not been initiated before **[insert date 90 days after date of public inspection]**, the Federal external review process established pursuant to this paragraph (d) applies only to:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(iii) Examples. This rules of paragraph (d)(1)(ii) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual A seeks coverage for a 31st physical therapy visit. A's health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, A receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) Conclusion. In this Example 1, the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) Facts. A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual B seeks coverage for a specialized medical procedure from an out-of-network provider because B believes that the procedure cannot be effectively provided in network. B receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) Conclusion. In this Example 2, the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(3) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

* * * * *

(2) * * *

(iv) These standards will provide that an external review decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide any benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

* * * * *

(e) Form and manner of notice – (1) In general. For purposes of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) Requirements – (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

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

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

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