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29 CFR Part 2590

**Department of Health and
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45 CFR Part 147

**Interim Final Rules for Group Health
Plans and Health Insurance Issuers
Relating to Internal Claims and Appeals
and External Review Processes Under the
Patient Protection and Affordable Care
Act; Interim Final Rule**

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 54 and 602**

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OCIO-9993-IFC]

45 CFR Part 147

RIN 0991-AB70

Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act

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

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains 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 the Patient Protection and Affordable Care Act. The regulations will generally affect health insurance issuers; group health plans; and participants, beneficiaries, and enrollees in health insurance coverage and in group health plans. The regulations provide plans and issuers with guidance necessary to comply with the law.

DATES: *Effective date.* These interim final regulations are effective on September 21, 2010.

Comment date. Comments are due on or before September 21, 2010.

Applicability dates. These interim final regulations generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations

generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010.

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

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

Department of Labor. Comments to the Department of Labor, identified by RIN 1210-AB45, by one of the following methods:

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

- *E-mail:* [E- OHPSCA2719.EBSA@dol.gov](mailto:EHPSA2719.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 <http://www.regulations.gov> and <http://www.dol.gov/ebsa>, and available for public inspection at the Public Disclosure Room, N-1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIO-9993-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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: Office of Consumer Information and Insurance Oversight,

Department of Health and Human Services, Attention: OCIO-9993-IFC, P.O. Box 8016, Baltimore, MD 21244-1850.

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

3. *By express or overnight mail.* You may send written comments to the following address only: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIO-9993-IFC, 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—Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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

- 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 (410) 786-7195 in advance to schedule your arrival with one of our staff members.

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

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

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in

a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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

Internal Revenue Service. Comments to the IRS, identified by REG-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, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (301) 492-4100.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp) and information on health reform can be found at <http://www.healthreform.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111-152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.¹ The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724² (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or

requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers requirements that are stricter than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations in several phases implementing the revised PHS Act sections 2701 through 2719A and related provisions of the Affordable Care Act. The first phase in this series was the publication of a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718, published in the **Federal Register** on April 14, 2010 (75 FR 19297). The second phase was interim final regulations implementing PHS Act section 2714 (requiring dependent coverage of children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third phase was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on June 17, 2010 (75 FR 34538). The fourth phase was interim final regulations implementing PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections), published in the **Federal Register** on June 28, 2010 (75 FR 37188). The fifth phase was interim final regulations implementing PHS Act section 2713 (regarding preventive health services), published in the **Federal Register** on July 19, 2010 (75 FR 41726). These interim final regulations are being published to implement PHS Act section 2719, relating to internal claims and appeals and external review processes. PHS Act section 2719 is generally effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

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

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

II. Overview of the Regulations: PHS Act Section 2719, Internal Claims and Appeals and External Review Processes (26 CFR 54.9815–2719T, 29 CFR 2590.715–27109, 45 CFR 147.136)

a. Scope and Definitions

These interim final regulations set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes for group health plans and health insurance coverage; these requirements do not apply to grandfathered health plans under section 1251 of the Affordable Care Act. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 provides that plans and issuers must initially incorporate the internal claims and appeals processes set forth in 29 CFR 2560.503–1 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 Health and Human Services. These interim final regulations provide such updated standards for compliance. The Department of Labor is also considering further updates to 29 CFR 2560.503–1 and expects to issue future regulations that will propose additional, more comprehensive updates to the standards for plan internal claims and appeals processes.

With respect to external review, PHS Act section 2719 provides a system for applicability of either a State external review process or a Federal external review process. These regulations provide rules for determining which process applies, as well as guidance regarding each process. Consistent with the statutory structure, these interim final regulations adopt an approach that builds on applicable State external review processes. For plans and issuers subject to existing State external review processes, the regulations include a transition period until July 1, 2011. During this period, the State process applies and the Departments will work individually with States on an ongoing basis to assist in making any necessary changes to incorporate additional consumer protections so that the State process will continue to apply after the end of the transition period. For plans and issuers not subject to an existing State external review process (including self-insured plans), a Federal process

will apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The Departments will be issuing more guidance in the near future on the Federal external review process.

These interim final regulations also set forth rules related to the form and manner of providing notices in connection with internal claims and appeals and external review processes. The regulations also reiterate and preserve the Departments' authority, pursuant to PHS Act section 2719(c), to deem external review processes in operation on March 23, 2010, to be in compliance with the requirements of PHS Act section 2719, either permanently or temporarily.

Paragraph (a)(2) of 26 CFR 54.9815–2719T, 29 CFR 2590.715–2719, 45 CFR 147.136 sets forth definitions relevant for these interim final regulations, including the definitions of an adverse benefit determination and a final internal adverse benefit determination. An adverse benefit determination is defined by incorporating the definition under the Department of Labor's regulations governing claims procedures at 29 CFR 2560.503–1 (DOL claims procedure regulation), and also includes a rescission of coverage. A final internal adverse benefit determination is the upholding of an adverse benefit determination at the conclusion of the internal appeals process or an adverse benefit determination with respect to which the internal appeals process has been deemed exhausted.

b. Internal Claims and Appeals Process

Paragraph (b) of 26 CFR 54.9815–2719T, 29 CFR 2590.715–2719, 45 CFR 147.136 requires group health plans and health insurance issuers offering group or individual health insurance coverage to implement an effective internal claims and appeals process. The regulations set forth separate rules for group health coverage and individual health insurance coverage.

1. Group Health Plans and Health Insurance Issuers Offering Group Health Insurance Coverage

A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under the DOL claims procedure regulation. Therefore, for purposes of compliance with these interim final regulations, a health insurance issuer offering health insurance coverage in connection with a group health plan is subject to the DOL claims procedure regulation to the same extent as if it were a group health plan.

These interim final regulations also set forth six new requirements in addition to those in the DOL claims procedure regulation.

First, for purposes of these interim final regulations, the definition of an adverse benefit determination is broader than the definition in the DOL claims procedure regulation, in that an adverse benefit determination for purposes of these interim final regulations also includes a rescission of coverage. By referencing the DOL claims procedure regulation, an adverse benefit determination eligible for internal claims and appeals processes under these interim final regulations includes a denial, reduction, or termination of, or a failure to provide or make a payment (in whole or in part) for a benefit, including any such denial, reduction, termination, or failure to provide or make a payment that is based on:

- A determination of an individual's eligibility to participate in a plan or health insurance coverage;
- A determination that a benefit is not a covered benefit;
- The imposition of a preexisting condition exclusion, source-of-injury exclusion, network exclusion, or other limitation on otherwise covered benefits; or
- A determination that a benefit is experimental, investigational, or not medically necessary or appropriate.

A denial, reduction, or termination of, or a failure to provide or make a payment (in whole or in part) for a benefit can include both pre-service claims (for example, a claim resulting from the application of any utilization review), as well as post-service claims. Failure to make a payment in whole or in part includes any instance where a plan pays less than the total amount of expenses submitted with regard to a claim, including a denial of part of the claim due to the terms of a plan or health insurance coverage regarding copayments, deductibles, or other cost-sharing requirements.³ Under these interim final regulations, an adverse benefit determination also includes any rescission of coverage as defined in the regulations restricting rescissions (26 CFR 54.9815–2712T(a)(2), 29 CFR 2590.715–2712(a)(2), and 45 CFR 147.128(a)(2)), whether or not there is an adverse effect on any particular benefit at that time. The regulations restricting rescissions generally define a rescission as a cancellation or discontinuance of coverage that has

³ See the Department of Labor's Frequently Asked Questions (FAQs) About the Benefit Claims Procedure Regulations, FAQ C–12, at <http://www.dol.gov/ebsa>.

retroactive effect, except to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

Rescissions of coverage must also comply with the requirements of the regulations restricting rescissions.⁴

Second, these interim final regulations provide 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)⁵ 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 health insurance coverage, 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.⁶ This is a change from the requirements of 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 Departments expect that electronic communication will enable faster decision-making today than in the year 2000, when the final DOL claims procedure regulation was issued.

Third, these interim final regulations provide additional criteria to ensure that a claimant receives a full and fair review. Specifically, in addition to complying with the requirements of the DOL claims procedure regulation, the plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or

issuer) in connection with the claim.⁷ Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date. Additionally, before the plan or issuer can issue an adverse benefit determination on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. The rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

Fourth, these interim final regulations provide new criteria with respect to avoiding conflicts of interest. The plan or issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support a denial of benefits. For example, a plan or issuer cannot provide bonuses based on the number of denials made by a claims adjudicator. Similarly, a plan or issuer cannot contract with a medical expert based on the expert's reputation for outcomes in contested cases, rather than based on the expert's professional qualifications.

Fifth, these interim final regulations provide new standards regarding notice to enrollees. Specifically, the statute and these interim final regulations require a plan or issuer to provide notice to enrollees, in a culturally and linguistically appropriate manner (standards for which are described later in this preamble). Plans and issuers must comply with the requirements of paragraphs (g) and (j) of the DOL claims procedure regulation, which detail

requirements regarding the issuance of a notice of adverse benefit determination.⁸ Moreover, for purposes of these interim final regulations, additional content requirements apply for these notices. A plan or issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved. This includes the date of service, the health care provider, and the claim amount (if applicable)⁹, as well as the diagnosis code (such as an ICD-9 code, ICD-10 code, or DSM-IV code)¹⁰, the treatment code (such as a CPT code)¹¹, and the corresponding meanings of these codes. A plan or issuer must also ensure that 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)¹² 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. Additionally, the plan or issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal. Finally, the plan or issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist enrollees with the

⁴ These regulations generally provide that a plan or issuer must not rescind coverage with respect to an individual once the individual is covered, except in the case of an act, practice, or omission that constitutes fraud, or an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage.

⁵ 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.

⁶ In the case of a failure to provide sufficient information, under the DOL claims procedure regulation the claimant must be notified as soon as possible, but not later than 24 hours after receipt of the claim, of the specific information necessary to complete the claim. The claimant must be afforded a reasonable amount of time, taking into account the circumstances, but not less than 48 hours, to provide the specified information.

⁷ This language underscores and is not inconsistent with the scope of the disclosure requirement under the existing Department of Labor claims procedure regulation. That is, the Department of Labor interprets 29 USC 1133 and the DOL claims procedure regulation as already requiring that plans provide claimants with new or additional evidence or rationales upon request and an opportunity to respond in certain circumstances. See Brief of amicus curiae Secretary of the United States Department of Labor, *Midgett v. Washington Group International Long Term Disability Plan*, 561 F.3d 887 (8th Cir. 2009) (No.08-2523) (expressing disagreement with cases holding that there is no such requirement).

⁸ Paragraph (g) of the DOL claims procedure regulation requires that the notice must be written in a manner calculated to be understood by the claimant and generally must include any specific reasons for the adverse determination, reference to the specific provision on which the determination is based, a description of any additional information required to perfect the claim, and a description of the internal appeal process. Paragraph (i) of the DOL claims procedure regulation requires that the notice must also be provided in accordance with specified timeframes for urgent care claims, pre-service claims, and post-service claims.

⁹ 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.

¹⁰ 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.

¹¹ CPT refers to Current Procedural Terminology.

¹² CARC refers to Claim Adjustment Reason Code and RARC refers to Remittance Advice Remark Code.

internal claims and appeals and external review processes. The Departments intend to issue model notices that could be used to satisfy all the notice requirements under these interim final regulations in the very near future. These notices will be made available at <http://www.dol.gov/ebsa> and <http://www.hhs.gov/ociio/>.

Sixth, these interim final regulations provide that, in the case of a plan or issuer that fails to strictly adhere to all the requirements of the internal claims and appeals process with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process, regardless of whether the plan or issuer asserts that it substantially complied with these requirements or that any error it committed was de minimis. Accordingly, upon such a failure, the claimant may initiate an external review and pursue any available remedies under applicable law, such as judicial review.

In addition to the six new requirements, the statute and these interim final regulations require a plan and issuer to provide continued coverage pending the outcome of an internal appeal. For this purpose, the plan or issuer must comply with the requirements of the DOL claims procedure regulation, which, as applied under these interim final regulations, generally prohibits a plan or issuer from reducing or terminating an ongoing course of treatment without providing advance notice and an opportunity for advance review. Additionally, individuals in urgent care situations and individuals receiving an ongoing course of treatment may be allowed to proceed with expedited external review at the same time as the internal appeals process, under either a State external review process or the Federal external review process, in accordance with the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners (NAIC Uniform Model Act). The provision of the NAIC Uniform Model Act requiring simultaneous internal appeals and external review is discussed later in this preamble.

2. Health Insurance Issuers Offering Individual Health Insurance Coverage

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

comply with all the requirements for the internal claims and appeals process that apply to group health coverage.¹³ The process and protections of the group health coverage standards are also pertinent to the individual health insurance market. Furthermore, many issuers in the individual market also provide coverage in the group market. To facilitate compliance, it is preferable to have similar processes in the group and individual markets. Accordingly, an individual health insurance issuer is subject to the DOL claims procedure regulation as if the issuer were a group health plan. Moreover, an individual health insurance issuer must also comply with the additional standards in these interim final regulations imposed on group health insurance coverage.

To address certain relevant differences in the group and individual markets, health insurance issuers offering individual health insurance coverage must comply with three additional requirements. First, these interim final regulations expand the scope of the group health coverage internal claims and appeals process to cover initial eligibility determinations for individual health insurance coverage. This protection is important because eligibility determinations in the individual market are frequently based on the health status of the applicant, including preexisting conditions. With the prohibition against preexisting condition exclusions taking effect for policy years beginning on or after September 23, 2010 for children under 19 and for all others for policy years beginning on or after January 1, 2014, applicants in the individual market should have the opportunity for a review of a denial of eligibility of coverage to determine whether the issuer is complying with the new provisions in making the determination.

Second, although the DOL claims procedure regulation permits plans to have a second level of internal appeals, these interim final regulations require that health insurance issuers offering individual health insurance coverage have only one level of internal appeals. This allows the claimant to seek either external review or judicial review immediately after an adverse benefit determination is upheld in the first level of the internal appeals process. There is no need for a second level of an internal appeal in the individual market since

¹³ The special rules in the DOL claims procedure regulation applicable only to multiemployer plans (generally defined in section 3(37) of ERISA as plans maintained pursuant to one or more collective bargaining agreements for the employees of two or more employers) do not apply to health insurance issuers in the individual market.

the issuer conducts all levels of the internal appeal, unlike in the group market, where a third party administrator may conduct the first level of the internal appeal and the employer may conduct a second level of the internal appeal. Accordingly, after an issuer has reviewed an adverse benefit determination once, the claimant should be allowed to seek external review of the determination by an outside entity.

Finally, these interim final regulations require health insurance issuers offering individual health insurance coverage to maintain records of all claims and notices associated with their internal claims and appeals processes. The records must be maintained for at least six years, which is the same requirement for group health plans under the ERISA recordkeeping requirements. An issuer must make such records available for examination upon request. Accordingly, a claimant or State or Federal agency official generally would be able to request and receive such documents free of charge. Other Federal and State law regarding disclosure of personally identifiable health information may apply, including the HIPAA privacy rule.¹⁴

c. State Standards for External Review

The statute and these interim final regulations provide that plans and issuers must comply with either a State external review process or the Federal external review process. These interim final regulations provide a basis for determining when plans and issuers must comply with an applicable State external review process and when they must comply with the Federal external review process.

For health insurance coverage, if a State external review process that applies to and is binding on an issuer includes, at a minimum, the consumer protections in the NAIC Uniform Model Act in place on July 23, 2010,¹⁵ then the issuer must comply with the applicable State external review process and not with the Federal external review process. In such a case, to the extent that benefits under a group health plan are provided through health insurance

¹⁴ See 45 CFR 164.500 *et seq.*

¹⁵ These interim final regulations specify that the relevant NAIC Uniform Model Act is the version in place on the date these interim final regulations are published. If the NAIC Uniform Model Act is later modified, the Departments will review the changes and determine to what extent any additional requirements will be incorporated into the minimum standards for State external review processes by amending these regulations. This version of the NAIC Uniform Model Act is available at <http://www.dol.gov/ebsa> and <http://www.hhs.gov/ociio/>.

coverage, the issuer is required to satisfy the obligation to provide an external review process, so the plan itself is not required to comply with either the State external review process or the Federal external review process. The Departments encourage States to establish external review processes that meet the minimum consumer protections of the NAIC Uniform Model Act. The Departments prefer having States take the lead role in regulating health insurance issuers, with Federal enforcement only as a fallback measure.

These interim final regulations do not preclude a State external review process from applying to and being binding on a self-insured group health plan under some circumstances. While the preemption provisions of ERISA ordinarily would prevent a State external review process from applying directly to an ERISA plan, ERISA preemption does not prevent a State external review process from applying to some self-insured plans, such as nonfederal governmental plans and church plans not covered by ERISA preemption, and multiple employer welfare arrangements, which can be subject to both ERISA and State insurance laws. A State external review process could apply to such plans if the process includes, at a minimum, the consumer protections in the NAIC Uniform Model Act.

Under these interim final regulations, any plan or issuer not subject to a State external review process must comply with the Federal external review process. (However, to the extent a plan provides health insurance coverage that is subject to an applicable State external review process that provides the minimum consumer protections in the NAIC Uniform Model Act, the plan does not have to comply with the Federal external review process.) A plan or issuer is subject to the Federal external review process where the State external review process does not meet, at a minimum, the consumer protections in the NAIC Uniform Model Act, as well as where there is no applicable State external review process.

For a State external review process to apply instead of the Federal external review process, the Affordable Care Act provides that the State external review process must include, at a minimum, the consumer protections of the NAIC Uniform Model Act. Accordingly, the Departments have determined that the following elements from the NAIC Uniform Model Act are the minimum consumer protections that must be included for a State external review process to apply. The State process must:

- Provide for the external review of adverse benefit determinations (and final internal adverse benefit determinations) that are based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.
- Require issuers to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.
- To the extent the State process requires exhaustion of an internal claims and appeals process, make exhaustion unnecessary if: the issuer has waived the exhaustion requirement, the claimant has exhausted (or is considered to have exhausted) the internal claims and appeals process under applicable law, or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.
- Provide that the issuer against which a request for external review is filed must pay the cost of an independent review organization (IRO) for conducting the external review. While having the issuer pay the cost of the IRO's review is reflected in the NAIC Uniform Model Act, if the State pays this cost, the Departments would treat the State process as meeting this requirement; this alternative is just as protective to the consumer because the cost of the review is not imposed on the consumer. Notwithstanding this requirement that the issuer (or State) must pay the cost of the IRO's review, the State process may require a nominal filing fee from the claimant requesting an external review. For this purpose, to be considered nominal, a filing fee must not exceed \$25, it must be refunded to the claimant if the adverse benefit determination is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single year must not exceed \$75.
- Not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review (for example, a \$500 minimum claims threshold).
- Allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.
- Provide that an IRO will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (for example, rotational assignment) by a State or

independent entity, and in no event selected by the issuer, plan, or individual.

- Provide for maintenance of a list of approved IROs qualified to conduct the review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

- Provide that any approved IRO has no conflicts of interest that will influence its independence.

- Allow the claimant to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and require that the claimant is notified of such right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer within one business day of receipt by the IRO.

- Provide that the decision 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.

- Provide that, for standard external review, within no more than 45 days after the receipt of the request for external review by the IRO, the IRO must provide written notice to the issuer and the claimant of its decision to uphold or reverse the adverse benefit determination.

- Provide for an expedited external review in certain circumstances and, in such cases, the State process must provide notice of the decision as expeditiously as possible, but not later than 72 hours after the receipt of the request.

- Require that issuers include a description of the external review process in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to claimants, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

- Require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

- Follow procedures for external review of adverse benefit determinations involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

The Departments invite comments on this list of minimum consumer

protections and whether other elements of the NAIC Uniform Model Act should be included in the list.

The Department of Health and Human Services will determine whether a State external review process meets these requirements (and thus whether issuers (and, if applicable, plans) subject to the State external review process must comply with the State external review process rather than the Federal external review process). A transition period will be provided, however, during which existing State external review processes may be treated as satisfying these requirements.

Under PHS Act section 2719, if a State external review process does not provide the minimum consumer protections of the NAIC Uniform Model Act, health insurance issuers in the State must implement the Federal external review process. The Departments' initial review of existing State external review processes indicates that not all State external review processes provide the minimum consumer protections of the NAIC Uniform Model Act. Under PHS Act section 2719(c), the Departments are provided with discretion to consider an external review process in place on the date of enactment of the Affordable Care Act to be in compliance with the external review requirement under section 2719(b) "as determined appropriate." 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 these interim final regulations, the Departments are using their authority under PHS Act section 2719(c) to treat existing State external review processes as meeting the minimum standards during a transition period for plan years (in the individual market, policy years) beginning before July 1, 2011.

Thus, for plan or policy years beginning before July 1, 2011, a health insurance issuer subject to an existing State external review process must comply with that State external review process and not the Federal external review process. The applicable external review process for plan or policy years beginning on or after July 1, 2011 depends on the type of coverage and whether the State external review process has been determined by the Department of Health and Human Services to satisfy the minimum standards of the NAIC Uniform Model Act.

The applicable external review process for any particular claim is based on the external review process

applicable to the plan or issuer at the time a final internal adverse benefit determination (or, in the case of simultaneous internal appeals and external review, the adverse benefit determination) is provided. For this purpose, the final internal adverse benefit determination includes a deemed final internal adverse benefit determination in which the internal claims and appeals process is exhausted because of the failure by the plan or issuer to comply with the requirements of the internal claims and appeals process. Thus, for an issuer with a calendar year plan year in a State in which the State external review process fails to meet the minimum standards, external review of final internal adverse benefit determinations provided prior to the first day of the first calendar year on or after July 1, 2011 (that is, January 1, 2012) must comply with the State external review process, while external reviews of final internal adverse benefit determinations provided on or after January 1, 2012 must meet the alternative Federal external review requirements.

An additional provision of the NAIC Uniform Model Act not addressed in the interim final regulations is the required scope of an applicable State external review process. The NAIC Uniform Model Act applies to all issuers in a State. The Departments' initial review of existing State external review processes indicates that some States do not apply the State external review process to all issuers in the State. For example, some State external review processes only apply to HMOs and do not apply to other types of health coverage. The Departments believe that State external review processes are more effective, and thus more protective, where the external review process is market-wide and available to all claimants with insured coverage. As States with external review processes decide whether to enact legislation amending their laws to provide the consumer protections that would satisfy the requirements of these interim final regulations, the Departments encourage States to establish external review processes that are available for all insured health coverage. This is consistent with the Departments general approach of having States take a lead role in providing consumer protections, with Federal enforcement only as a fallback measure.

That said, these interim final regulations do not set a specific standard for availability of the State external review process that is considered to meet the minimum consumer protections of the NAIC Uniform Model Act. If it is determined

that market-wide application of the State external review process is required, plans and issuers would be subject to the Federal external review process in States that do not apply the State external review process to all issuers in the State. Alternatively, if it is determined that universal availability is not required, those plans and issuers that are not subject to the State external review process would be, as are self-insured plans, subject to the Federal external review process. The Departments seek comments whether the Federal external review process should apply to all plans and issuers in a State if the State external review process does not apply to all issuers in the State. After reviewing the comments, the Departments expect to issue future guidance addressing the issue.

d. Federal External Review Process

PHS Act section 2719(b)(2) requires the Departments to establish standards, "through guidance," governing an external review process that is similar to the State external appeals process that meets the standards in these regulations. These interim final regulations set forth the scope of claims eligible for review under the Federal external review process. Specifically, under the Federal external review process, the terms "adverse benefit determination" and "final internal adverse benefit determination" are defined the same as they are for purposes of internal claims and appeals (and, thus, include rescissions of coverage). However, an adverse benefit determination or final internal adverse benefit determination that relates 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) is not within the scope of the Federal external review process.

These interim final regulations set forth the standards that would apply to claimants, plans, and issuers under this Federal external review process, and the substantive standards that would be applied under this process. They also reflect the statutory requirement that the process established through guidance from the Departments be similar to a State external review process that complies with the standards in these regulations. They also provide that the Federal external review process, like the State external review process, will provide for expedited external review and additional consumer protections with respect to external review for claims involving experimental or investigational treatment. The

Departments will address in sub-regulatory guidance how non-grandfathered self-insured group health plans that currently maintain an internal appeals process that otherwise meets the Federal external review standards may comply or be brought into compliance with the requirements of the new Federal external review process.

e. Culturally and Linguistically Appropriate

The statute and these interim final regulations require that notices of available internal claims and appeals and external review processes be provided in a culturally and linguistically appropriate manner. Plans and issuers are considered to provide relevant notices in a culturally and linguistically appropriate manner if notices are provided in a non-English language as described these interim final regulations.¹⁶ Under these interim final regulations, the requirement to provide notices in a non-English language is based on thresholds of the number of people who are literate in the same non-English language. In the group market, the threshold 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. The thresholds are adapted from the Department of Labor's regulations regarding style and format for a summary plan description, at 29 CFR 2520.102-2(c). In the individual market, the threshold is 10 percent of the population residing in the county being literate only in the same non-English language.¹⁷ The Department of Health and Human Services will publish guidance that issuers may consult to

¹⁶ For internal claims involving urgent care (for which the claim is generally made by a health care provider), where paragraph (g) of the DOL claims procedure regulation permits an initial oral notice of determination must be made within 24 hours and follow-up in written or electronic notification within 3 days of the oral notification, it may not be reasonable, practicable, or appropriate to provide notice in a non-English language within 24 hours. In such situations, the requirement to provide notice in a culturally and linguistically appropriate manner is satisfied if the initial notice is provided in English and the follow-up notice is provided in the appropriate non-English language.

¹⁷ The county-by-county approach is generally adapted from the approach used under the Medicare Advantage program.

establish these county level estimates on its Web site at <http://www.hhs.gov/ociio/> by September 23, 2010. The Department of Health and Human Services welcomes comments on whether the threshold should remain 10 percent and whether it should continue to be applied on a county-by-county basis.

If an applicable threshold is met, notice must be provided upon request in the non-English language with respect to which the threshold is met. In addition, the plan or issuer must also 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. Once a request has been made by a claimant, the plan or issuer must provide all subsequent notices to a claimant in the non-English language. In addition, 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.

f. Secretarial Authority

The statute provides the Departments with the authority to deem an external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, to be in compliance with PHS Act section 2719. These interim final regulations provide the Departments may determine that the external review process of a plan or issuer, in operation as of March 23, 2010, is considered in compliance with a State external review process or the Federal external review process, as applicable.

g. Applicability Date

The requirements to implement effective internal and external claims and appeals processes apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations do not apply to grandfathered health plans. See 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 (75 FR 34538, June 17, 2010).

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the

provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, the internal claims and appeals and external review provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Moreover, the requirements in these interim final regulations require significant lead time in order to implement. These interim final regulations require plans and issuers to provide internal claims and appeals and external review processes and to notify participants, beneficiaries, and enrollees of their rights to such processes. Plans and issuers will presumably need to amend current internal claims and appeals procedures, adopt new external review processes, and notify participants, beneficiaries, and enrollees of these changes before they go into effect. Moreover, group health plans and health insurance issuers subject to these provisions will have to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits. In some cases,

issuers will need time to secure approval for these changes in advance of the plan or policy year in question.

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

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

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

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

IV. Economic Impact and Paperwork Burden

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

As stated earlier in this preamble, these interim final regulations implement PHS Act section 2719, which sets 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.¹⁸ This provision generally is effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act.

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

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

Under Executive Order 12866 (58 FR 51735), “significant” regulatory actions

are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a “significant regulatory action” as an action that is likely to result in a rule (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. OMB has determined that this rule is significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an effect on the economy of \$100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order. The Departments provide an assessment of the potential costs and benefits of each regulatory provision below, summarized in table 1.

TABLE 1—ACCOUNTING TABLE

Benefits:

Qualitative: A more uniform, rigorous, and consumer friendly system of claims and appeals processing will provide a broad range of direct and indirect benefits that will accrue to varying degrees to all of the affected parties. These interim final regulations could improve the extent to which employee benefit plans provide benefits consistent with the established terms of individual plans. While payment of these benefits will largely constitute transfers, the transfers will be welfare improving, because incorrectly denied benefits will be paid. Greater certainty and consistency in the handling of benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated should lead to efficiency gains in the system, both in terms of the allocation of spending across plans and enrollees as well as operational efficiencies among individual plans. This certainty and consistency can also be expected to benefit, to varying degrees, all parties within the system, particularly consumers, and to lead to broader social welfare gains.

	Estimate	Year dollar	Discount rate	Period covered
Costs:				
Annualized Monetized (\$millions/year)	51.2	2010	7%	2011–2013
	51.6	2010	3%	2011–2013

Qualitative: The Departments have quantified the primary source of costs associated with these interim final regulations that will be incurred to (i) administer and conduct the internal and external review process, (ii) prepare and distribute required disclosures and notices, and (iii) bring plan and issuers’ internal and external claims and appeals procedures into compliance with the new requirements. The Departments also have quantified the start-up costs for issuers in the individual market to bring themselves into compliance.

Reversals:

Annualized Monetized (\$millions/year)	24.4	2010	7%	2011–2013
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¹⁸The Affordable Care Act adds Section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A

of title XXVII of the PHS Act applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, under ERISA and the Code

as if those provisions of the PHS Act were included in ERISA and the Code.

	Estimate	Year dollar	Discount rate	Period covered
	24.7	2010	3%	2011–2013

Qualitative: The Departments estimated the dollar amount of claim denials reversed in the external review process. While this amount is a cost to plans, it represents a payment of benefits that should have previously been paid to participants, but was denied. Part of this amount is a transfer from plans and issuers to those now receiving payment for denied benefits. These transfers will improve equity, because incorrectly denied benefits will be paid. Part of the amount could also be a cost if the reversal leads to services and hence resources being utilized now that had been denied previously. The Departments are not able to distinguish between the two types, but believe that most reversals are associated with a transfer.

1. Need for Regulatory Action

Before the enactment of the Affordable Care Act, health plan sponsors and issuers were not uniformly required to implement claims and appeals processes. For example, ERISA-covered group health plan sponsors were required to implement internal claims and appeal processes that complied with the DOL claims procedure regulation,¹⁹ while group health plans that were not covered by ERISA, such as plans sponsored by State and local governments were not. Health insurance issuers offering coverage in the individual insurance market were required to comply with various applicable State internal appeals laws but were not required to comply with the DOL claims procedure regulation.

With respect to external appeal processes, before the enactment of the Affordable Care Act, sponsors of fully-insured ERISA-covered group health plans, fully-insured State and local governmental plans, and fully-insured church plans were required to comply with State external review laws, while self-insured ERISA-covered group health plans were not subject to such laws due to ERISA preemption.²⁰ In the individual health insurance market, issuers in States with external review laws were required to comply with such laws. However, uniform external review standards did not apply, because State external review laws vary from State-to-State. Moreover, at least six States did not have external review laws when the Affordable Care Act was enacted; therefore, issuers in those States were not required to implement an external review process.

Under this regulatory system, inconsistent claims and appeals processes applied to plan sponsors and

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

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

2. PHS Act Section 2719—Claims and Appeals Process (26 CFR 54.9815–2719T, 29 CFR 2590.715–2719, 45 CFR 147.136)

a. Summary

As discussed earlier in this preamble, section 1001 of the Affordable Care Act adds new PHS Act section 2719, which requires all non-grandfathered group health plans and health insurance issuers offering group or individual health coverage to implement uniform internal claims and appeals and external appeals processes. Under PHS Act section 2719 and these interim final regulations, all sponsors of non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage

must comply with all requirements of the DOL claims procedures regulation²¹ as well as the new standards that are established by the Secretary of Labor and the Secretary of Health and Human Services in paragraphs (b)(2) and (b)(3) of these interim final regulations.

On the external appeals side, all group health plans or health insurance issuers offering group or individual health insurance coverage that are not grandfathered must comply with an applicable State external review process that, at a minimum, includes the consumer protections set forth in the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners (the “NAIC Uniform Model Act”) and is binding on the plan or issuer. If the State has not established an external review process that meets the requirements of the NAIC Uniform Model Act or a plan is not subject to State insurance regulation, (including a State law that establishes an external review process) because it is a self-insured plan, the plan or issuer must comply with the requirements of a Federal external review process set forth in paragraph (d) of these interim final regulations.

b. Estimated Number of Affected Entities

For purposes of the new requirements in the Affordable Care Act that apply to group health plans and health insurance issuers in the group and individual markets, 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 interim final regulations: (1) There are approximately 72,000 large and 2.8 million small ERISA-covered group health plans with

²¹ Please note that under these interim final regulations, the individual health insurance market is not required to comply with the requirements of the Department of Labor’s claims and appeals procedure regulation that apply to multiemployer plans.

¹⁹ 29 CFR 2560.503–1.

²⁰ To the extent that the ERISA preemption provisions do not prevent a State external review process from applying to a self-insured plan (for example, for self-insured nonfederal governmental plans, self-insured church plans, and self-insured multiple employer welfare arrangements) the State could make its external review process applicable to them. The Departments are unaware of the number of these plans that are subject to State external review laws.

an estimated 97.0 million participants in large group plans and 40.9 million participants in small group plans;²² (2) there are 126,000 governmental plans with 36.1 million participants in large plans and 2.3 million participants in small plans;²³ and (3) there are 16.7 million individuals under age 65 covered by individual health insurance policies.²⁴

As described in the Departments' interim final regulations relating to status as a grandfathered health plan,²⁵ the Affordable Care Act preserves the ability of individuals to retain coverage under a group health plan or health insurance coverage in which the individual was enrolled on March 23, 2010 (a grandfathered health plan). Group health plans and individual health insurance coverage that are grandfathered health plans do not have to meet the requirements of these interim final regulations. Therefore, only plans and issuers offering group and individual health insurance coverage that are not grandfathered health plans will be affected by these interim final regulations.

Plans can choose to make certain disqualifying changes and relinquish their grandfather status.²⁶ The Affordable Care Act provides plans with the ability to maintain grandfathered status in order to promote stability for consumers while allowing plans and sponsors to make reasonable adjustments to lower costs and encourage the efficient use of services. Based on an analysis of the changes plans have made over the past few years, the Departments expect that more plans will choose to make these changes over time and therefore the number of grandfathered health plans is expected to decrease. Correspondingly, the number of plans and policies affected by these interim final regulations is likely to increase over time. In addition, the number of individuals receiving the full benefits of the Affordable Care Act is likely to increase over time. The Departments estimate that 18 percent of large employer plans and 30 percent of small employer plans would relinquish grandfather status in 2011, increasing over time to 45 percent and 66 percent respectively by 2013, although there is

substantial uncertainty surrounding these estimates.²⁷ The Departments also estimate that in 2011, roughly 31 million people will be enrolled in group health plans subject to PHS Act section 2719 and these interim final regulations, growing to approximately 78 million in 2013.²⁸

In the individual market, one study estimated that 40 percent to 67 percent of individual policies terminate each year.²⁹ Because newly purchased individual policies are not grandfathered, the Departments expect that a large proportion of individual policies will not be grandfathered, covering up to and perhaps exceeding 10 million individuals.

Not all potentially affected individuals will be affected equally by these interim final regulations. As stated in the Need for Regulatory Action section above, sponsors of ERISA-covered group health plans were required to implement an internal appeals process that complied with the DOL claims procedure regulation before the Affordable Care Act's enactment, and the Departments also understand that many non-Federal governmental plans and church plans that are not subject to ERISA nonetheless implement internal claims and appeals processes that comply with the DOL claims procedure regulation.³⁰ Therefore,

²⁷ See 75 FR 34538 (June 17, 2010) for a detailed description of the derivation of the estimates for the percentages of grandfathered health plans. In brief, the Departments used data from the 2008 and 2009 Kaiser Family Foundations/Health Research and Educational Trust survey of employers to estimate the proportion of plans that made changes in cost-sharing requirements that would have caused them to relinquish grandfather status if those same changes were made in 2011, and then applied a set of assumptions about how employer behavior might change in response to the incentives created by the grandfather regulations to estimate the proportion of plans likely to relinquish grandfather status. The estimates of changes in 2012 and 2013 were calculated by using the 2011 calculations and assuming that an identical percentage of plan sponsors will relinquish grandfather status in each year.

²⁸ To estimate the number of individuals covered in grandfathered health plans, the Departments extended the analysis described in 75 FR 34538, and estimated a weighted average of the number of employees in grandfathered health plans in the large employer and small employer markets separately, weighting by the number of employees in each employer's plan. Estimates for the large employer and small employer markets were then combined, using the estimates supplied above that there are 133.1 million covered lives in the large group market, and 43.2 million in the small group market.

²⁹ Adele M. Kirk. *The Individual Insurance Market: A Building Block for Health Care Reform? Health Care Financing Organization Research Synthesis*. May 2008.

³⁰ This understanding is based on the Departments' conversations with industry experts. In addition, the Departments understand that ERISA-covered plans, State and local government

participants and beneficiaries covered by such plans only will be affected by the new internal claims and appeals standards that are provided by the Secretary of Labor in paragraph (b)(2)(ii) of these interim final regulations.

These interim final regulations will have the largest impact on individuals covered in the individual health insurance market, because as discussed earlier in this preamble, for the first time, these issuers will be required to comply with the DOL claims procedure regulation for internal claims and appeals as well as the additional standards added by the Secretary of the Department of Health and Human Services in paragraph (b)(3) of these interim final regulations that are in some cases more protective than the ERISA standard.³¹

On the external appeals side, before the enactment of the Affordable Care Act, issuers offering coverage in the group and individual health insurance market already were required to comply with State external review laws. At that time, all States except Alabama, Mississippi, Nebraska, North Dakota, South Dakota, and Wyoming had external review laws, and thirteen States had external review laws that apply only to certain market segments (for example, managed care or HMOs). Therefore, the extent to which enrollees covered by policies issued by these issuers will be affected by these interim final regulations depends on whether the applicable State external review law complies with the minimum consumer protections set forth in the NAIC Uniform Model Act, because if it does not, the policies will become subject to the Federal external review process that applies to self-insured plans that are not subject to State regulation³² and plans

and non-ERISA covered church plans generally use the same insurance issuers and service providers who apply the ERISA claims and appeals requirements to all types of plans.

³¹ To address certain relevant differences in the group and individual markets, health insurance issuers offering individual health insurance coverage must comply with the following three additional requirements: (1) Expand the scope of the claims and appeals process to cover initial eligibility determinations; (2) provide only one level of internal appeal (although the DOL claims procedure regulation permits group health plans to have a second level of internal appeals), which allows claimants to seek either an external appeal or judicial review immediately after an adverse determination is upheld in the first level of internal appeal; and (3) maintain records of all claims and notices associated with their internal claims and appeals processes and make such records available for examination upon request by claimants and Federal or State regulatory officials.

³² To the extent that the ERISA preemption provisions do not prevent a State external review process from applying to a self-insured plan (for example, for self-insured nonfederal governmental plans, self-insured church plans, and self-insured

²² 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.

²³ Estimate is from the 2007 Census of Government.

²⁴ U.S. Census Bureau, Current Population Survey, March 2009.

²⁵ 75 FR 34538 (June 17, 2010).

²⁶ See 75 FR 34538 (June 17, 2010).

and policies in States that do not have external review laws that meet the minimum consumer protections set forth in the NAIC Uniform Model Act.

Individuals participating in ERISA-covered self-insured group health plans will be among those most affected by the external review requirements contained in these interim final regulations, because the preemption provisions of ERISA prevent a State's external review process from applying directly to an ERISA-covered self-insured plan.³³ These plans now will be required to comply with the Federal external review process set forth under paragraph (d) of these interim final regulations.

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

c. Benefits

In developing these interim final regulations, the Departments closely considered their potential economic effects, including both costs and benefits. Because of data limitations and a lack of effective measures, the Departments did not attempt to quantify expected benefits. Nonetheless, the Departments were able to identify with confidence several of the interim final regulation's major economic benefits.

These interim final regulations will help transform the current, highly variable health claims and appeals process into a more uniform and structured process. As stated in the Need for Regulatory Action above, before the enactment of the Affordable Care Act, inconsistent internal and external claims and appeals standards applied to plan sponsors and issuers, and a patchwork of consumer protections were provided to participants, beneficiaries, and enrollees that depended on several factors including whether (i) Plans were subject

to ERISA, (ii) benefits were self-funded or financed by the purchase of an insurance policy, (iii) issuers were subject to State internal claims and appeals laws, and (iv) issuers were subject to State external review laws, and if so, the scope of such laws (such as, whether the laws only apply to one segment of the health insurance market, *e.g.*, managed care or HMO coverage).

A more uniform, rigorous, and consumer friendly system of claims and appeals processing will provide a broad range of direct and indirect benefits that will accrue to varying degrees to all of the affected parties. In general, the Departments expect that these interim final regulations will improve the extent to which employee benefit plans provide benefits consistent with the established terms of individual plans. This will cause some participants to receive benefits that, absent the fuller protections of the regulation, they might otherwise have been incorrectly denied. In other circumstances, expenditures by plans may be reduced as a fuller and fairer system of claims and appeals processing helps facilitate enrollee acceptance of cost management efforts. Greater certainty and consistency in the handling of benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated may lead to efficiency gains in the system, both in terms of the allocation of spending at a macro-economic level as well as operational efficiencies among individual plans. This certainty and consistency can also be expected to benefit, to varying degrees, all parties within the system and to lead to broader social welfare gains, particularly for consumers.

By making claims and appeals processes more uniform, these interim final regulations will increase efficiency in the operation of employee benefit plans and health care delivery as well as health insurance and labor markets. These interim final regulations are expected to increase efficiency by reducing complexity that arises when different market segments are subject to varying claims and appeals standards. Idiosyncratic requirements, time-frames, and procedures for claims processing impose substantial burdens on participants, their representatives, and service providers. By establishing a more uniform and complete set of minimum requirements and consumer protections, these interim final regulations will reduce the complexity of claims and appeals processing requirements, thereby increasing efficiency.

The Departments expect that these interim final regulations also will improve the efficiency of health plans by enhancing their transparency and fostering participants' confidence in their fairness. When information about the terms and conditions under which benefits will be provided is unavailable to enrollees, they could discount the value of benefits to compensate for the perceived risk. The enhanced disclosure and notice requirements of these interim final regulations will help participants, beneficiaries, and enrollees better understand the reasons underlying adverse benefit determinations and their appeal rights.

The Departments believe that excessive delays and inappropriate denials of health benefits are relatively rare. Most claims are approved in a timely fashion. Many claim denials and delays are appropriate given the plan's terms and the circumstances at hand. Nonetheless, to the extent that delays and inappropriate denials occur, substantial harm can be suffered by participants, beneficiaries, and enrollees, which can also lead to an associated loss of confidence in the fairness and benefits of the system. A more timely and complete review process required under these interim final rules regulations should reduce the levels of delay and error in the system and improve health outcomes.

The voluntary nature of the employment-based health benefit system in conjunction with the open and dynamic character of labor markets make explicit as well as implicit negotiations on compensation a key determinant of the prevalence of employee benefits coverage. The prevalence of benefits is therefore largely dependent on the efficacy of this exchange. If workers perceive that there is the potential for inappropriate denial of benefits or handling of appeals, they will discount the value of such benefits to adjust for this risk. This discount drives a wedge in compensation negotiation, limiting its efficiency. With workers unwilling to bear the full cost of the benefit, fewer benefits will be provided. To the extent that workers perceive that these interim final regulations, supported by enforcement authority, reduces the risk of inappropriate denials of benefits, the differential between the employers' costs and workers' willingness to accept wage offsets is minimized.

Effective claims procedures also can improve health care, health plan quality, and insurance market efficiency by serving as a communication channel, providing feedback from participants, beneficiaries, and providers to plans

multiple employer welfare arrangements) the State could make its external review process applicable to such plans if it includes, at a minimum, the consumer protections in the NAIC Uniform Model Act.

³³ While it is possible that some ERISA-covered self-insured plans may have adopted external review procedures as a matter of good business practice, the Departments are uncertain regarding the level to which this has occurred.

about quality issues. Aggrieved claimants are especially likely to disenroll if they do not understand their appeal rights, or if they believe that their plans' claims and appeals procedures will not effectively resolve their difficulties. Unlike appeals, however, disenrollments fail to alert plans to the difficulties that prompted them. More uniform and effective appeals procedures can give participants and beneficiaries an alternative way to respond to difficulties with their plans. Plans in turn can use the information gleaned from the appeals process to improve services.

The Departments also expect that these interim final regulations' higher standard for more uniform internal and external claims appeals adjudication will enhance some insurers' and group health plans' abilities to effectively control costs by limiting access to inappropriate care. Providing a more formally sanctioned framework for internal and external review and consultation on difficult claims facilitates the adoption of cost containment programs by employers who, in the absence of a regulation providing some guidance, may have opted to pay questionable claims rather than risk alienating participants or being deemed to have breached a fiduciary duty.

In summary, the interim final regulations' more uniform standards for handling health benefit claims and appeals will reduce the incidence of excessive delays and inappropriate denials, averting serious, avoidable lapses in health care quality and resultant injuries and losses to participant, beneficiaries and enrollees. They also will enhance enrollees' level of confidence in and satisfaction with their health care benefits and improve plans' awareness of participant, beneficiary, and provider concerns, prompting plan responses that improve health care quality. Finally, by helping to ensure prompt and precise adherence to contract terms and by improving the flow of information between plans and enrollees, the interim final regulations will bolster the efficiency of labor, health care, and insurance markets. The Departments therefore conclude that the economic benefits of these interim final regulations will justify their costs.

d. Costs and Transfers

The Departments have quantified the primary source of costs associated with these interim final regulations that will be incurred to (i) Administer and conduct the internal and external review process, (ii) prepare and distribute required disclosures and

notices, and (iii) bring plan and issuers' internal and external claims and appeals procedures into compliance with the new requirements. The Departments also have quantified the start-up costs for issuers in the individual market to bring themselves into compliance and the costs and the transfers associated with the reversal of denied claims during the external review process. These costs and the methodology used to estimate them are discussed below.

i. *Internal Claims and Appeals.* As discussed above, these interim final regulations require all group health plans and issuers offering coverage in the group and individual health insurance market to comply with the DOL claims procedure regulation. The ERISA-covered market, with an estimated 2.8 million plans and 138 million covered participants, already is required to comply with the DOL claims procedure regulation and is far larger than either the non-Federal governmental plan market, with an estimated 126,000 governmental plans and 30 million participants, or the individual market, with 16.7 million participants. As stated in the Estimated Number of Affected Entities section, the Departments understand that many non-Federal governmental plans comply with the DOL claims procedure regulation, because they use the same issuers and service providers as ERISA-covered plans, and these issuers and service providers implement the internal claims and appeals process for plans in both markets. Therefore, for purposes of this regulatory impact analysis, the Departments assume that 90 percent of the claims volume in the non-Federal governmental group health plan market already complies with the DOL claims procedure regulation.³⁴

The Departments estimate that 170 issuers offer policies only in the individual market.³⁵ While the Departments believe that some issuers are subject to applicable state laws governing internal appeals processes, and have evidence that some issuers already comply with the DOL claims procedure regulation, some issuers will have to change their internal claims and

³⁴ The Departments are uncertain regarding the 90 percent compliance rate for State and local government plans. Therefore, to establish a range, the Departments estimated the cost assuming 75 percent State and local governmental plan compliance. Assuming 75 percent compliance, the cost of State and local plan internal review compliance would increase from \$2 million to \$5 million in 2011, \$3.6 million to \$9.1 million in 2012, and \$5 million to \$12.4 million in 2012.

³⁵ Source: Estimates are from NAIC 2007 financial statements data and the California Department of Managed Healthcare (2009) (<http://wpso.dmh.ca.gov/hpsearch/viewall.aspx>).

appeals processes to comply with these interim final regulations.³⁶ The Departments estimate that issuers would incur a start-up cost of \$3.5 million in the first year to comply with these interim final regulations by revising processes, creating or revising forms, modifying systems, and training personnel. These costs are mitigated by the model notice of initial benefit determination the Departments will be issuing in subregulatory guidance. This notice will not require any data to be provided that cannot be automatically populated by plans and issuers.

ii. *Cost Required to Implement DOL Claims Procedure Regulation Requirements.* The Departments' estimates of the annual costs for plans and issuers to comply with the DOL claims procedure regulation are based on the methodology used for the Paperwork Reduction Act (PRA) hour and cost burden analysis of DOL claims procedure regulation.³⁷ The Department first estimated the number of individuals covered by non-grandfathered plans using the March 2009 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey. Each covered individual was estimated to generate 10.2 claims on average per year,³⁸ 82 percent of which were filed electronically.³⁹ The Departments then assumed that 15 percent of these claims were denied.⁴⁰ The Departments assume that three percent of these claims were pre-service with the remaining being post-service claims.⁴¹ The number of post-service claims extended was based on the share

³⁶ Discussions with the National Association of Insurance Commissioners suggest that three States require issuers in the individual market to follow the NAIC internal grievance appeals model. Eleven States have no set procedures in place, while the rest have varying requirements. Some issuers voluntarily follow the ERISA claims and appeals procedures.

³⁷ The OMB Control Number for the DOL procedure regulation is 1210-0053. OMB approved the three-year renewal of the Control Number through May 31, 2013, on May 21, 2010.

³⁸ Research at the time of the Claims Regulation as well as responses to the Claims RFI reported a wide range of claims per participant—between 5 and 18. The Department eventually settled on 10.2.

³⁹ AHIP, "Update: A Survey of Health Care Claims Receipt and Processing Times, 2009," January 2010.

⁴⁰ Health Insurance Association of America (HIAA, which later merged with AHIP) reported a denial rate of 14 percent in "Results from an HIAA Survey on Claims Payment Process," March 2003. These included duplicate claims as well as denied claims that were appeals. RAND reported an increased trend in claim denials in, "Inside the Black Box of Managed Care Decisions," Research Brief, 2004 from 3 percent to between 8 and 10 percent.

⁴¹ The assumption that 3 percent of claims are pre-service is based on comments the Department received in response to the proposed DOL claims procedure regulation in 2000.

of “clean” claims that took more than 30 days to complete processing.⁴² The share of denials expected to be appealed, 0.2 percent, was based on a RAND study.⁴³ The Departments expect half of these appeals to be reversed,⁴⁴ and those not reversed were divided between “medical claims” (28.9 percent) and “administrative claims” (71.1 percent).

The Departments attributed costs to notifying individuals of denied claims and processing appeals. Initial denials were assumed to only take a few minutes for a clerical worker to draft and send an adverse benefit determination notice based on the model notice that will be issued by the Departments that does not require any information to be included that cannot

be auto-populated. Appealed denials deemed “medical” are assumed to require a physician, with an estimated labor rate of \$154.07 to review and was expected to take 4 ½ hours to decide and draft a response, regardless of outcome.⁴⁵ Appealed denials deemed “administrative” require a legal professional with an estimated labor rate of \$119.03, and a decision and response was expected to take two minutes for a reversal and two hours for a denial.⁴⁶ Mailing costs for the notice of adverse determination and notice of decision of internal appeal is estimated at 54 cents a notice for material, printing, and postage costs.

Because ERISA-covered plans already are required to comply with the DOL claims procedure regulation, the

Departments did not attribute any cost to these plans to comply with the rule. As stated above, the Departments understand from consulting with industry experts that a substantial majority of State and local government plans also currently comply with the existing DOL claims procedure regulation; therefore, the Departments assumed that only ten percent of the estimated claims of individuals covered by these plans would constitute a new expense. All claims in non-grandfathered plans in the individual market were assumed to bear the full cost of compliance, because these policies are being required to comply with the DOL claims procedure regulation for the first time. Table 2 shows the estimated number of claims.

TABLE 2—ESTIMATED CLAIMS AND APPEALS IN NON-GRANDFATHERED COVERAGE

	2011			2012			2013		
	Private sector ESI	Government sector ESI	Individual market	Private sector ESI	Government sector ESI	Individual market	Private sector ESI	Government sector ESI	Individual market
Total Enrollees (millions)	138.0	39.0	15.1	138.0	39.0	15.1	138.0	39.0	15.1
Non-Grandfathered Enrollees	24.4	6.9	6.0	44.5	12.6	9.7	61.0	17.2	11.8
Total Claims (millions)	248.9	70.4	61.5	453.8	128.3	98.5	622.4	175.9	120.6
Pre-Service:									
Claim Approved	6.3	1.8	1.6	11.6	3.3	2.5	15.9	4.5	3.1
Claim Denied	1.1	0.3	0.3	2.0	0.6	0.4	2.8	0.8	0.5
Post-Service:									
Claims Approved	196.2	55.5	45.2	357.8	101.1	72.3	490.7	138.7	88.6
Claim Denied	36.2	10.2	9.0	66.0	18.7	14.3	90.6	25.6	17.6
Claim Extended	9.0	2.5	5.6	16.4	4.6	8.9	22.5	6.3	10.9
Total Internal Appeals (thousands)	85.4	24.1	52.8	155.7	44.0	84.5	213.6	60.4	103.5
Appeals Upheld	34.2	9.7	21.1	62.3	17.6	33.8	85.4	24.1	41.4
Appeals Denied	51.2	14.5	31.7	93.4	26.4	50.7	128.1	36.2	62.1
Medical subtotal	24.7	7.0	15.3	45.0	12.7	24.4	61.7	17.4	29.9
Appeals Upheld	9.9	2.8	6.1	18.0	5.1	9.8	24.7	7.0	12.0
Appeals Denied	14.8	4.2	9.2	27.0	7.6	14.6	37.0	10.5	17.9
Administrative subtotal	60.7	17.2	37.5	110.7	31.3	60.1	151.8	42.9	73.6
Appeals Upheld	24.3	6.9	15.0	44.3	12.5	24.0	60.7	17.2	29.4
Appeals Denied	36.4	10.3	22.5	66.4	18.8	36.0	91.1	25.8	44.1
Total New External Appeals (thousands)	2.0	0.6	0.2	3.7	1.1	0.3	5.0	1.5	0.4

As shown in Table 3 below, the Departments estimate that the cost of the internal process, including the costs of internal appeals and notice distribution, is \$1.5 million in 2011 and rises to \$3.8 million in 2013 as the number of non-grandfathered plans increases. The Departments estimate that the cost for the internal review process for the individual market is \$28.8 million in 2011 and rises to \$56.4 million in 2013.

iii. Additional Requirements for Group Health Plans. As discussed

⁴² AHIP, “Update: A Survey of Health Care Claims Receipt and Processing Times, 2009,” January 2010.

⁴³ “Inside the Black Box of Managed Care Decisions,” Research Brief, 2004.

⁴⁴ The Department based this assumption on the number of appealed Medicare pre-authorization denials. They received comments for the proposed regulation arguing this estimate was either too high

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

or too low and so the Department chose to retain the assumption.

⁴⁵ The Department in its initial claims regulation assumed that an expert consultation would cost \$500 which translated into roughly 5 hours of a physician’s time. EBSA has revised this slightly downward based on the costs reported by IROs to review medical claims.

requirements and their associated costs are discussed below.

Definition of adverse determination. These interim final regulations expand the definition of adverse benefit determination to include rescissions of coverage. While new, the methodology used to estimate the burden for the internal appeals process already captures this burden as most rescissions are associated with a claim and therefore would already be accounted for. The requirement allows for appeal of rescinded coverage that does not have

⁴⁶ The Departments’ estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

an associated claim. While the Departments lack data to estimate the number of rescissions that occur without an associated claim for benefits, the Departments believe this number is small.

Expedited notification of benefit determination involving urgent care. The current DOL claims procedure regulation requires that a plan or issuer provide notification in the case of an urgent care claim as soon as possible taking into account the medical exigencies, but no later than 72 hours after receipt of the claim by the plan. These interim final regulations reduce the time limit to no later than 24 hours after the receipt of the claim by the plan or issuer. The Departments are not able to quantify the costs of this requirement. However, two factors could suggest this requirement does not impose substantial cost. First, the DOL claims procedure regulation requires urgent care notification to be made as soon as possible; therefore, it is likely that some claims currently are handled in less than the 24 hours. In addition, the technological developments that have occurred since the 72 hour standard was issued in the 2000 DOL claims procedure regulation should facilitate faster notification at reduced costs. However, plans and issuers would incur additional cost for urgent care notices that take longer than the required 24 hours to produce. Speeding up the notification process for these determinations might necessitate incurring additional cost to add more employees or find other ways to shorten the timeframe. Additional costs may be associated with this requirement if a shorter timeframe results in claims being denied that would not have been under a 72 hour standard or claims being approved that would have been denied under a longer notification period.

Full and fair review. These interim final regulations require the plan or issuer to provide the claimant, free of charge, with any new or additional evidence relied upon or generated by the plan or issuer and the rationale used for a determination during the appeals process sufficiently in advance of the due date of the response to an adverse benefit determination. This requirement increases the administrative burden on plans and issuers to prepare and deliver the new and additional information to the claimant. The Departments are not aware of data suggesting how often plans rely on new or additional evidence during the appeals process or the volume of materials that are received.

For purposes of this regulatory impact analysis, the Departments assume, as an upper bound, that all appealed claims will involve a reliance on additional evidence. The Departments assume that this requirement will impose a cost of just under \$1 million in 2013, the year with the highest cost. The Departments estimated this cost by assuming that it will require medical office staff with a labor rate of \$26.85 five minutes⁴⁷ to collect and distribute the additional evidence considered, relied on, or generated during the appeals process. The Departments estimate that on average, material, printing and postage costs will be \$2.24 per mailing. The Departments further assume that 38 percent of all mailings will be distributed electronically with no associated material, printing or postage costs.⁴⁸

Eliminating conflicts of interest. As discussed earlier in this preamble, these interim final regulations require plans and issuers to ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood or perceived likelihood that the individual will support or tend to support the denial of benefits.

This requirement could require plans or issuers to change policies that currently create a conflict of interest and to discontinue practices that create such conflicts. The Departments believe that many plans and issuers already have such requirements in place as a matter of good business practice, but do not have sufficient data to provide an estimate. However, the Departments believe that the cost associated with this requirement will be minimal.

Enhanced notice. These interim final regulations provide new standards regarding notice to enrollees. Specifically, the statute and these interim final regulations require a plan or issuer to provide notice to enrollees, in a culturally and linguistically appropriate manner (standards for which are described later in this

preamble). Plans and issuers must comply with the requirements of paragraphs (g) and (j) of the DOL claims procedure regulation, which detail requirements regarding the issuance of a notice of adverse benefit determination. Moreover, for purposes of these interim final regulations, additional content requirements apply for these notices. A plan or issuer must ensure that any notice of adverse benefit determination or final adverse benefit determination includes information sufficient to identify the claim involved. This includes 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. A plan or issuer must also ensure that description of the reason or reasons for the denial includes a description of the standard that was used in denying the claim. In the case of a notice of final adverse benefit determination, this description must include a discussion of the decision. Additionally, the plan or issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal. Finally, the plan or issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist such enrollees with the internal claims and appeals and external review process. The Departments intend to issue model notices that could be used to satisfy all the notice requirements under these interim final regulations in the very near future that will mitigate the cost associated with providing them. These notices will be made available at <http://www.dol.gov/ebsa> and <http://www.hhs.gov/ociio/>. The cost of sending the notices is included in the costs of the internal and external review process. The Departments were unable to estimate the cost of providing the model notices in a linguistically and culturally appropriate manner. However the Departments believe the overall costs to be small as only a small number of plans are believed to be affected. The Departments request comments that could help in estimating these costs, particularly with respect to the individual insurance market.

Deemed exhaustion of internal process. These interim final regulations provide that, in the case of a plan or issuer that fails to strictly adhere to all the requirements of the internal claims

⁴⁷ EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

⁴⁸ This estimate is based on the methodology used to analyze the cost burden for the DOL claims procedure regulation (OMB Control Number 1210-0053).

and appeals process with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process, regardless of whether the plan or issuer asserts that it substantially complied with these requirements or that the error was de minimis. Accordingly, under such deemed exhaustion, the claimant may initiate an external review and pursue any available remedies under applicable law, such as judicial review. The Departments are unable to quantify the costs that are associated with this requirement. While this provision possibly could result in an increased number of external appeals it could reduce overall costs if costly litigation is avoided.

Continued coverage. Finally, the statute and these interim final regulations require a plan and issuer to provide continued coverage pending the outcome of an internal appeal. For this purpose, the plan or issuer must comply with the requirements of paragraph (f)(2)(ii) of the DOL claims procedure regulation, which generally provide that a plan or issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review. Moreover, as described more fully earlier in this preamble, the plan or issuer must also provide simultaneous external review in advance of a reduction or termination of an ongoing course of treatment.

This provision would not impose any additional cost on plans and issuers that comply with the DOL claims procedure regulation; however, costs would be incurred by issuers in the individual market. The Departments are unable to quantify the cost associated with this requirement, because they lack sufficient data on the number of simultaneous reviews that are conducted.⁴⁹

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

⁴⁹ The Departments do not have a basis to estimate this, because the Departments do not know how often this denial takes place or how often they are appealed. The costs should be minimal, because the decisions will be made quickly, and the period of coverage will be brief. The Departments expect the cost to be small relative to the cost of reversals, which the Departments have estimated.

This protection is important since eligibility determinations in the individual market are frequently based on the health status of the applicant, including preexisting conditions. The Departments do not have sufficient data to quantify the costs associated with this requirement.⁵⁰

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

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

v. External Appeals. The analysis of the cost associated with implementing an external review process under these interim final regulations focuses on the cost incurred by the following three groups that were not required to implement an external review process before the enactment of the Affordable Care Act: plans and participants in ERISA-covered self-insured plans; plans and participants in States with no external review laws, and plans and participants in States that have State laws only covering specific market segment (usually HMOs or managed care coverage).

The Departments estimate that there are about 76.9 million participants in self-insured ERISA-covered plans and approximately 13.8 million participants

⁵⁰ However, the Departments believe this number to be small. Approximately 10 to 15 percent of applicants are declined coverage in the individual market, while the Departments do not know how many of those denied coverage will appeal, using appeal rates for internal and external appeals would result in only a few thousand appeals. See "Fundamentals of Underwriting in the nongroup Health Insurance Market," pages 10–12, April 13, 2005.

in self-insured State and local governmental plans. In the States which currently have no external review laws there are an estimated 4.2 million participants (2.5 million participants in ERISA-covered plans, 1.2 million participants in governmental plans and 0.6 million in individual with policies in the individual market). In the States that currently have limited external review laws, there are 15.6 million participants (8.4 million participants in ERISA-covered plans, 4.2 million participants in governmental plans and 3.0 million individuals with individual health insurance in the individual market). These estimates lead to a total of 110.5 million participants, however, only the 44.2 million participants in non-grandfathered plans will be newly covered by the external review requirement in 2011. As plans relinquish their grandfather status in subsequent years, more individuals will be covered.

The Departments assume that there are an estimated 1.3 external appeals for every 10,000 participants,⁵¹ and that there will be approximately 2,600 external appeals in 2011. As required by these interim final regulations or applicable State law, plans or issuers are required to pay for most of the cost of the external review while claimants may be charged a modest filing fee. A recent report finds that the average cost of a review was approximately \$605.⁵² While the actual cost per review will vary by state and also type of review (standard or expedited), an older study covering many States suggests this is a reasonable estimate.⁵³ These estimates lead to an estimated cost of the external review of \$1.6 million (2,600 reviews * \$605) in 2011. Using a similar method and adjusting for the number of non-grandfathered plans in subsequent years, the Departments estimate that the total cost for external review is \$2.9 million in 2012 and \$3.9 million in 2013.

On average, about 40 percent of denials are reversed on external appeal.⁵⁴ An estimate of the dollar

⁵¹ AHIP Center for Policy and Research, "An Update on State External Review Programs, 2006," July 2008.

⁵² North Carolina Department of Insurance "Healthcare Review Program: Annual Report," 2008.

⁵³ Pollitz, Karen, Jeff Crowley, Kevin Lucia, and Eliza Bangit "Assessing State External Review Programs and the Effects of Pending Federal Patient's Rights Legislation." Kaiser Family Foundation (2002) page 27.

⁵⁴ AHIP Center for Policy and Research, "An Update on State External Review Programs, 2006," July 2008.

amount per claim reversed in \$12,400.⁵⁵ This leads to \$13.4 million in additional claims being reversed by the external review process in 2011, which increases to \$33.1 million in 2013. While this amount is a cost to plans, it represents a payment of benefits that should have previously been paid to participants, but was denied. Part of this amount is a transfer from plans and issuers to those now receiving payment for denied benefits. Part of the amount could also be a cost if the reversal leads to services and hence resources being utilized now that had been denied previously. The Departments are not able to distinguish

between the two types but believe that most reversals are associated with a transfer.

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

3. Summary

These interim final rules extend the protections of the DOL claims procedure

regulation to non-Federal governmental plans, and the market for individual coverage. Additional protections are added that cover these two markets and also the market for ERISA covered plans. These interim final regulations also extend the requirement to provide an independent external review. The Departments estimate that the total costs for these interim final regulations is \$50.4 million in 2011, \$78.8 million in 2012, and \$101.1 million in 2013. The estimates are summarized in table 3, below.

TABLE 3—MONETIZED IMPACTS OF INTERIM FINAL REGULATIONS
[In millions]

	2011	2012	2013
ERISA Market	\$1.4	\$2.5	\$3.5
External Review	1.2	2.2	3.1
Internal Review *	0.0	0.0	0.0
Fair and Full Review	0.2	0.3	0.4
State & Local Government Market	2.4	4.3	6.0
External Review	0.4	0.6	0.9
Internal Review **	2.0	3.6	5.0
Fair and Full Review	0.05	0.1	0.1
Individual Market	32.5	46.4	56.8
External Review	0.1	0.2	0.2
Internal Review	28.8	46.0	56.4
Fair and Full Review	0.1	0.2	0.2
Recordkeeping	0.1	0.1	0.1
Start-up Costs	3.5	0.0	0.0
Total Costs	36.2	53.2	66.2
Amount of Reversals***	14.2	25.6	34.9
ERISA Plans	10.3	18.7	25.7
State & Local Government Plans	3.0	5.4	7.4
Individual Market	0.9	1.5	1.9

* Assumes that ERISA plans already comply with ERISA claims and appeals regulations.

** Assumes that 90 percent of State and Local Government plans already comply with the ERISA claims and appeals regulation.

*** This amount includes both transfers and costs with identical offsetting benefits.

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. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B or title I of ERISA, and part A of title XXVII of the

PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

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

significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

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

D. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human

⁵⁵ North Carolina Department of Insurance “Healthcare Review Program: Annual Report,” 2008.

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

E. Paperwork Reduction Act

1. Department of Labor and Department of the Treasury

As discussed above in the Department of Labor and Department of the Treasury PRA section, these interim final regulations require group health plans and health insurance issuers offering group or individual health insurance coverage to comply with the DOL claims procedure regulation with updated standards. They also require such plans and issuers to implement an external review process.

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 e-mail to oir_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: ebssa.opr@dol.gov. ICRs submitted to OMB also are available at [reginfo.gov](http://www.reginfo.gov/public/do/PRAMain) (<http://www.reginfo.gov/public/do/PRAMain>).

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

As discussed earlier in this preamble, under PHS Act section 2719 and these interim final regulations, all sponsors of non-grandfathered group health plans and health insurance issuers offering group health insurance coverage must comply with all requirements of the DOL claims procedure regulation (29 CFR 2560.503-1) as well as the new standards in paragraph (b)(2)(ii) of these interim final regulations.

Before the enactment of the Affordable Care Act, ERISA-covered group health plans already were required to comply with the requirements of the DOL claims procedure regulation. The DOL claims procedure regulation requires, among other things, plans to provide a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. The Departments are not soliciting comments concerning an information collection request (ICR) pertaining to the requirement for ERISA-covered group health plans to meet the disclosure requirements of DOL's claims procedure regulation, because the costs and burdens associated with complying with

these provisions already are accounted for under the Department of Labor's Employee Benefit Plan Claims Procedure Under ERISA regulation (OMB Control Number 1210-0053).

Additional hour and cost burden is associated with paragraph (b)(2)(ii)(C) of these interim final regulations, which requires non-grandfathered ERISA-covered group health plans to provide the claimant, free of charge, with any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim.⁵⁶ This requirement increases the administrative burden on plans and issuers to prepare and deliver the additional information to the claimant.

Additional hour and cost burden also is associated with the requirement in paragraphs (c) and (d) of the regulations which set forth the external review requirements. The requirement for group health plans to implement an external review process will impose an hour and cost burden on plans that were not required to implement such a process before the enactment of the Affordable Care Act, such as self-insured plans, plans in states with no external review laws, and plans in states with limited scope external review laws (such as laws that only impact specific market segments like HMOs).

The Departments estimate that approximately 93 percent of large benefit and all small benefit plans administer claims using a third-party provider, or roughly 5 percent of covered individuals. In-house administration burdens are accounted for as hours, while purchased services are accounted for as dollar costs. Based on the foregoing, total burden hours are estimated at 300 hours in 2011, 500 hours in 2012, and 700 hours in 2013. Equivalent costs are \$11,000, \$19,000, and \$26,000 respectively.

As stated in the preceding paragraph, the bulk of claims will be processed by third-party service providers. Total cost is estimated by multiplying the number of responses by the amount of time required to prepare the documents and then multiplying this by the appropriate hourly cost of either clerical workers

⁵⁶ Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date. Additionally, before the plan or issuer can issue an adverse benefit determination on review based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. The rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

(\$26.14) or doctors (\$154.07),⁵⁷ and then adding the cost of copying and mailing responses (\$0.54 each for those not sent electronically). Based on the foregoing, the Departments estimate that the total estimated cost burden for those plans that use service providers, including the cost of mailing all responses (including mailing costs for those prepared in-house listed in Table 2), is \$243,000 in 2011, \$443,000 in 2012, and \$607,000 in 2013.

Type of Review: New 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: 607,000.

Total Responses: 62,000.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 150 hours (Employee Benefits Security Administration); 150 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: \$121,500 (Employee Benefits Security Administration); \$121,500 (Internal Revenue Service).

2. Department of Health and Human Services

As discussed above in the Department of Labor and Department of the Treasury PRA section, these interim final regulations require group health plans and health insurance issuers offering group or individual health insurance coverage to comply with the DOL claims procedure regulation with updated standards. They also require such plans and issuers to implement an external review process.

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

As discussed earlier in the preamble, paragraph (b)(2) and (b)(3) of these

interim final regulations require all group health plan sponsors and health insurance issuers offering coverage in the group and individual health insurance markets to comply with the requirements of DOL's claims procedure regulation for their internal claims and appeals processes. Plan sponsors and issuers offering coverage in the group market also are required to satisfy the additional standards that are imposed on group health plans and issuers in paragraph (b)(2)(ii) of these interim final regulations, while issuers offering coverage in the individual health insurance market are required to satisfy the additional standards set forth in paragraph (b)(3)(ii) of these interim final regulations.

On the external review side, for purposes of this PRA analysis, the Department estimates the hour and cost burden for plans that were not previously subject to any external review requirements (self-insured plans, plans in states with no external review programs, and non-managed care plans in states that require external review only for managed care plans) to implement an external review process.

Based on the foregoing, the Department estimates that state and local governmental plans and issuers offering coverage in the individual market will incur a total hour burden hours of 566,000 hours in 2011, 989,000 hours in 2012, and 1.2 million hours in 2013 to comply with equivalent costs of \$28.1 million in 2011, \$57.1 million in 2012, and \$70.1 million in 2013. The total estimated 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, \$37.4 million in 2012, and \$51.1 million in 2013.

The hour and cost burden is summarized below:

Type of Review: New collection.

Agency: Department of Health and Human Services.

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

OMB Number: 0938-1098.

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

Respondents: 27,829.

Responses: 132,035,000.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 566,000 hours.

Estimated Total Annual Burden Cost: \$20,700,000.

b. ICR Regarding Affordable Care Act Recordkeeping Requirement for Non-Grandfathered Plans

As discussed earlier in this preamble, a health insurance issuer offering individual health insurance coverage must generally comply with all the requirements for the internal claims and appeals process that apply to group health coverage.⁵⁸ In addition to these standards, paragraph (b)(3)(ii)(H) of 45 CFR 147.136 requires health insurance issuers offering individual health insurance coverage to maintain records of all claims and notices associated with their internal claims and appeals processes. The records must be maintained for at least six years, which is the same requirement for group health plans under the ERISA recordkeeping requirements. An issuer must make such records available for examination upon request. Accordingly, a claimant or State or Federal agency official generally would be able to request and receive such documents free of charge.

The Department assumes that most of these records will be kept in the ordinary course of the issuers' business. Therefore, the Department estimates that the recordkeeping burden imposed by this ICR will require five minutes of a legal professional's time (with a rate of \$119.03/hour) to determine the relevant documents that must be retained and ten minutes of clerical staff time (with a labor rate of \$26.14/hour) to organize and file the required documents to ensure that they are accessible to claimants and Federal and State governmental agency officials. As shown in Table 4, below, overall, the Department estimates that there to be a total annual hour burden of 1,800 hours with an equivalent cost of \$105,000.

TABLE 4—TOTAL HOUR BURDEN AND EQUIVALENT COST

	Number (A)	Hours (B)	Hourly labor cost (C)	Hour burden A*B	Equivalent cost A*B*C
Record Keeping (attorney): Individual	7,350	0.08	\$119	613	\$72,906

⁵⁷EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008,

Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

⁵⁸The special rules in the DOL claims procedure regulation applicable only to multiemployer plans,

as described earlier in this preamble, do not apply to health insurance issuers in the individual market.

TABLE 4—TOTAL HOUR BURDEN AND EQUIVALENT COST—Continued

	Number (A)	Hours (B)	Hourly labor cost (C)	Hour burden A*B	Equivalent cost A*B*C
Record Keeping (clerical): Individual	7,350	0.17	26	1,225	32,022
Total				1,838	104,927

Because this burden is borne solely by the insurers offering coverage in the individual health insurance market, and these issuers are assumed to process all claims in-house, there is no annual cost burden associated with this collection of information.

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agency: Department of Health and Human Services.

Title: Affordable Care Act Recordkeeping Requirements.

OMB Number: 0938–1098.

Affected Public: For Profit Business.

Respondents: 490.

Responses: 7,350.

Frequency of Response: Occasionally.

Estimated Total Annual Burden

Hours: 1,800 hours.

Estimated Total Annual Burden Cost: \$0.

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

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

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

Attention: CMS Desk Officer, OCIIO–9994–IFC.

Fax: (202) 395 6974; or

E-mail:

OIRA_submission@omb.eop.gov.

F. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of \$100 million (as adjusted for inflation) by State, local and tribal

governments or the private sector. These interim final regulations are not subject to the Unfunded Mandates Reform Act because they are being issued as interim final regulations. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, the regulation has been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector, while achieving the objectives of the Affordable Care Act.

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 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, meeting with NAIC staff counsel on issues arising from these 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 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.

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

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

List of Subjects

26 CFR Part 54

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

29 CFR Part 2590

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

45 CFR Part 147

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

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: July 19, 2010.

Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 16th day of July 2010.

Phyllis C. Borzi,

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

Dated: July 19, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: July 19, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter 1

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

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding an entry for § 54.9815–2719T in numerical order to read in part as follows:

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

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

■ **Par. 2.** Section 54.9815–2719T is added to read as follows:

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

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 54.9815–1251T. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be

provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section. Paragraph (g) of this section sets forth the applicability date for this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 54.9815–2712T(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant.* *Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review.* *External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision*, as used in paragraph (d) of this section, means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization (or IRO)* means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act*. The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general*. A group health plan and a health insurance issuer offering group health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers*. A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards*. A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards*. In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination*. For purposes of this paragraph (b)(2), an “adverse benefit determination” includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage

are subject to the requirements of § 54.9815–2712T.)

(B) *Expedited notification of benefit determinations involving urgent care*. Notwithstanding the rule of 29 CFR 2560.503–1(f)(2)(i) that provides for notification in the case of urgent care claims not later than 72 hours after the receipt of the claim, for purposes of this paragraph (b)(2), a plan and 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, 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. The requirements of 29 CFR 2560.503–1(f)(2)(i) other than the rule for notification within 72 hours 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).

(C) *Full and fair review*. A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(1) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date.

(D) *Avoiding conflicts of interest*. In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must

ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice*. A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

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

(2) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan’s or issuer’s standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

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

(4) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*. In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), regardless of whether the plan or issuer asserts that it substantially complied

with the requirements of this paragraph (b)(2) or that any error it committed was de minimis. 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.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503-1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(c) *State standards for external review—(1) In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement, the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, the State external review process may require a nominal filing fee from the claimant requesting an external review. For this purpose, to be considered nominal, a filing fee must not exceed \$25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the

annual limit on filing fees for any claimant within a single plan year must not exceed \$75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a \$500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider

when conducting the external review and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the issuer (or, if applicable, the plan), as well as the claimant except to the extent that other remedies are available under State or Federal law.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the claimant and the issuer (or, if applicable, the plan) of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set

forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for existing external review processes*—(i) For plan years beginning before July 1, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of this paragraph (c). Accordingly, for plan years beginning before July 1, 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 after the first day of the first plan year beginning on or after July 1, 2011, 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 as of the first day of the plan year.

(d) *Federal external review process*. A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(1) *Scope*. 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 external review process under this paragraph (d).

(2) *External review process standards*. The Federal external review process established pursuant to this paragraph (d) will be similar to the process set forth in the NAIC Uniform Model Act and will meet standards issued by the Secretary. These standards will comply with all of the requirements described in this paragraph (d)(2).

(i) These standards will describe how a claimant initiates an external review, procedures for preliminary reviews to determine whether a claim is eligible for external review, minimum qualifications for IROs, a process for approving IROs eligible to be assigned to conduct external reviews, a process for random assignment of external reviews to approved IROs, standards for IRO decision-making, and rules for providing notice of a final external review decision.

(ii) These standards will provide an expedited external review process for—

(A) An adverse benefit determination, if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant, or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal under paragraph (b) of this section; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review pursuant to paragraph (d)(3) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility.

(iii) With respect to claims involving experimental or investigational treatments, these standards will also provide additional consumer protections to ensure that adequate clinical and scientific experience and protocols are taken into account as part of the external review process.

(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.

(v) These standards may establish external review reporting requirements for IROs.

(vi) These standards will establish additional notice requirements for plans and issuers regarding disclosures to participants and beneficiaries describing the Federal external review procedures (including the right to file a request for an external review of an adverse benefit determination or a final internal adverse benefit determination in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants or beneficiaries).

(vii) These standards will require plans and issuers to provide information relevant to the processing of the external review, including, but not limited to, the information considered and relied on in making the adverse benefit determination or final internal adverse benefit determination.

(e) *Form and manner of notice.* (1) For purposes of this section, a group health plan and health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner—

(i) For a plan that covers fewer than 100 participants at the beginning of a plan year, if the plan and issuer provide notices upon request in a non-English language in which 25 percent or more of all plan participants are literate only in the same non-English language; or

(ii) For a plan that covers 100 or more participants at the beginning of a plan year, if the plan and issuer provide notices upon request in a non-English language in which the lesser of 500 or more participants, or 10 percent or more of all plan participants, are literate only in the same non-English language.

(2) If an applicable threshold described in paragraph (e)(1) of this section is met, the plan and issuer must also—

(i) 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;

(ii) Once a request has been made by a claimant, provide all subsequent notices to the claimant in the non-English language; and

(iii) 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.

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

(g) *Applicability/effective date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 54.9815–1251T for determining the application of this section to grandfathered health plans (providing that these rules regarding internal claims and appeals and external review processes do not apply to grandfathered health plans).

(h) *Expiration date.* The applicability of this section expires on July 22, 2013 or on such earlier date as may be provided in final regulations or other action published in the **Federal Register**.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 3.** The authority citation for part 602 continues to read in part as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 4.** Section 602.101(b) is amended by adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

CFR part or section where identified and described	Current OMB control No.
* * * * *	
(b) * * *	
54.9815–2719T	1545–2182
* * * * *	

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

■ 29 CFR part 2590 is amended as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor’s Order 6–2009, 74 FR 21524 (May 7, 2009).

Subpart C—Other Requirements

■ 2. Section 2590.715–2719 is added to subpart C to read as follows:

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

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 2590.715–1251 of this part. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section. Paragraph (g) of this section sets forth the applicability date for this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 2590.715–2712(a)(2) of this part (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An appeal or internal appeal means review

by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant.* *Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review.* *External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision*, as used in paragraph (d) of this section, means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization (or IRO)* means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the

obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an “adverse benefit determination” includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 2590.715–2712 of this part.)

(B) *Expedited notification of benefit determinations involving urgent care.* Notwithstanding the rule of 29 CFR 2560.503–1(f)(2)(i) that provides for notification in the case of urgent care claims not later than 72 hours after the receipt of the claim, for purposes of this paragraph (b)(2), a plan and 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, 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. The requirements of 29 CFR 2560.503–1(f)(2)(i) other than the rule for notification within 72 hours 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).

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(1) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(1) The plan and issuer must ensure that any notice of adverse benefit

determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

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

(4) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), regardless of whether the plan or issuer asserts that it substantially complied with the requirements of this paragraph (b)(2) or that any error it committed was de minimis. 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.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For

this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503-1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's)

requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement, the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, the State external review process may require a nominal filing fee from the claimant requesting an external review. For this purpose, to be considered nominal, a filing fee must not exceed \$25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year must not exceed \$75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a \$500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IRO qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the issuer (or, if applicable, the plan), as well as the claimant except to the extent the other remedies are available under State or Federal law.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more

than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review timeframe would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for existing external review processes*—(i) For plan years beginning before July 1, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of this paragraph (c). Accordingly, for plan years beginning before July 1, 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 after the first day of the first plan year beginning on or after July 1, 2011, 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 as of the first day of the plan year.

(d) *Federal external review process*. A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(1) *Scope*. 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 external review process under this paragraph (d).

(2) *External review process standards*. The Federal external review process established pursuant to this paragraph (d) will be similar to the process set forth in the NAIC Uniform Model Act and will meet standards issued by the Secretary. These standards will comply with all of the requirements described in this paragraph (d)(2).

(i) These standards will describe how a claimant initiates an external review, procedures for preliminary reviews to determine whether a claim is eligible for external review, minimum qualifications for IROs, a process for

approving IROs eligible to be assigned to conduct external reviews, a process for random assignment of external reviews to approved IROs, standards for IRO decisionmaking, and rules for providing notice of a final external review decision.

(ii) These standards will provide an expedited external review process for—

(A) An adverse benefit determination, if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant, or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal under paragraph (b) of this section; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review pursuant to paragraph (d)(3) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay or health care service for which the claimant received emergency services, but has not been discharged from a facility.

(iii) With respect to claims involving experimental or investigational treatments, these standards will also provide additional consumer protections to ensure that adequate clinical and scientific experience and protocols are taken into account as part of the external review process.

(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.

(v) These standards may establish external review reporting requirements for IROs.

(vi) These standards will establish additional notice requirements for plans and issuers regarding disclosures to participants and beneficiaries describing the Federal external review procedures (including the right to file a request for an external review of an adverse benefit determination or a final internal adverse benefit determination in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants or beneficiaries.

(vii) These standards will require plans and issuers to provide information relevant to the processing of the external review, including, but not limited to, the information considered and relied on in making the adverse benefit determination or final internal adverse benefit determination.

(e) *Form and manner of notice.* (1) For purposes of this section, a group health plan and health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner—

(i) For a plan that covers fewer than 100 participants at the beginning of a plan year, if the plan and issuer provide notices upon request in a non-English language in which 25 percent or more of all plan participants are literate only in the same non-English language; or

(ii) For a plan that covers 100 or more participants at the beginning of a plan year, if the plan and issuer provide notices upon request in a non-English language in which the lesser of 500 or more participants, or 10 percent or more of all plan participants, are literate only in the same non-English language.

(2) If an applicable threshold described in paragraph (e)(1) of this section is met, the plan and issuer must also—

(i) 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;

(ii) Once a request has been made by a claimant, provide all subsequent notices to the claimant in the non-English language; and

(iii) 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.

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

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 2590.715–1251 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding internal claims and appeals and external

review processes do not apply to grandfathered health plans).

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 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Add § 147.136 to read as follows:

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 147.140 of this part. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section. Paragraph (g) of this section sets forth the applicability date for this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal)*. An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant*. *Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review*. *External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination*. A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) or (b)(3)(ii)(F) of this section).

(vi) *Final external review decision*. A *final external review decision*, as used in paragraph (d) of this section, means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO)*. An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act*. The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general*. A group health plan and a health insurance issuer offering group or individual health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers*. A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if

either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards*. A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards*. In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination*. For purposes of this paragraph (b)(2), an “adverse benefit determination” includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128 of this part.)

(B) *Expedited notification of benefit determinations involving urgent care*. Notwithstanding the rule of 29 CFR 2560.503–1(f)(2)(i) that provides for notification in the case of urgent care claims not later than 72 hours after the receipt of the claim, for purposes of this paragraph (b)(2), a plan and 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, 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. The requirements of

29 CFR 2560.503–1(f)(2)(i) other than the rule for notification within 72 hours 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).

(C) *Full and fair review*. A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(1) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date.

(D) *Avoiding conflicts of interest*. In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice*. A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional

requirements of this paragraph (b)(2)(ii)(E).

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

(2) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

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

(4) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), regardless of whether the plan or issuer asserts that it substantially complied with the requirements of this paragraph (b)(2) or that any error it committed was de minimis. 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.

(iii) *Requirement to provide continued coverage pending the outcome of an*

appeal. A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503-1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(3) *Requirements for individual health insurance issuers.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of this paragraph (b)(3).

(i) *Minimum internal claims and appeals standards.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of the ERISA internal claims and appeals procedures applicable to group health plans under 29 CFR 2560.503-1 except for the requirements with respect to multiemployer plans, and except to the extent those requirements are modified by paragraph (b)(3)(ii) of this section. Accordingly, under this paragraph (b), with respect to individual health insurance coverage, the issuer is subject to the requirements in 29 CFR 2560.503-1 as if the issuer were a group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(3)(i) of this section, the internal claims and appeals processes of a health insurance issuer offering individual health insurance coverage must meet the requirements of this paragraph (b)(3)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(3), an adverse benefit determination includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503-1, as well as other provisions of this paragraph (b)(3), an issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) and any decision to deny coverage in an initial eligibility determination as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of 45 CFR 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* Notwithstanding the rule of 29 CFR 2560.503-1(f)(2)(i) that provides for notification in the case of urgent care claims not later than 72 hours after the receipt of the claim, for purposes of this

paragraph (b)(3), an 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 issuer, unless the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the health insurance coverage. The requirements of 29 CFR 2560.503-1(f)(2)(i) other than the rule for notification within 72 hours continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503-1(m)(1).

(C) *Full and fair review.* An issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503-1(h)(2)—

(1) The issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the issuer (or at the direction of the issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503-1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(2) Before the issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503-1(i) to give the claimant a reasonable opportunity to respond prior to that date.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503-1(b) and (h) regarding full and fair review, the issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon

the likelihood that the individual will support the denial of benefits.

(E) *Notice.* An issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

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

(2) The issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

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

(4) The issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* In the case of an issuer that fails to strictly adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), regardless of whether the issuer asserts that it substantially complied with the requirements of this paragraph (b)(3) or that any error it committed was de minimis. 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 applicable State law on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(G) *One level of internal appeal.* Notwithstanding the requirements in 29 CFR § 2560.503–1(c)(3), a health insurance issuer offering individual health insurance coverage must provide for only one level of internal appeal before issuing a final determination.

(H) *Recordkeeping requirements.* A health insurance issuer offering individual health insurance coverage must maintain for six years records of all claims and notices associated with the internal claims and appeals process, including the information detailed in paragraph (b)(3)(ii)(E) of this section and any other information specified by the Secretary. An issuer must make such records available for examination by the claimant or State or Federal oversight agency upon request.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* An issuer subject to the requirements of this paragraph (b)(3) is required to provide continued coverage pending the outcome of an appeal. For this purpose, the issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii) as if the issuer were a group health plan, so that the issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.

(c) *State standards for external review—(1) In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group or individual health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal

external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement, the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) or (b)(3) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, the State external review process may require a nominal filing fee from the claimant requesting an external review. For this purpose, to be considered nominal, a filing fee must not exceed \$25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if

payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year (in the individual market, policy year) must not exceed \$75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a \$500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IRO qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the issuer (or, if applicable, the plan), as well as the claimant except to the extent the other remedies are available under State or Federal law.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the claimant and the issuer (or, if applicable, the plan) of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for existing external review processes*—(i) For plan years (in the individual market, policy years) beginning before July 1, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of this paragraph (c). Accordingly, for plan years (in the individual market, policy years) beginning before July 1, 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 after the first day of the first plan year (in the individual market, policy year) beginning on or after July 1, 2011, 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 as of the first day of the plan year (in the individual market, policy year).

(d) *Federal external review process*—A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer

with respect to the health insurance coverage.

(1) *Scope.* 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, 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 external review process under this paragraph (d).

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) will be similar to the process set forth in the NAIC Uniform Model Act and will meet standards issued by the Secretary. These standards will comply with all of the requirements described in this paragraph (d)(2).

(i) These standards will describe how a claimant initiates an external review, procedures for preliminary reviews to determine whether a claim is eligible for external review, minimum qualifications for IROs, a process for approving IROs eligible to be assigned to conduct external reviews, a process for random assignment of external reviews to approved IROs, standards for IRO decision-making, and rules for providing notice of a final external review decision.

(ii) These standards will provide an expedited external review process for—

(A) An adverse benefit determination, if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant, or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal under paragraph (b) of this section; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review pursuant to paragraph (d)(3) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay or

health care service for which the claimant received emergency services, but has not been discharged from a facility.

(iii) With respect to claims involving experimental or investigational treatments, these standards will also provide additional consumer protections to ensure that adequate clinical and scientific experience and protocols are taken into account as part of the external review process.

(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.

(v) These standards may establish external review reporting requirements for IROs.

(vi) These standards will establish additional notice requirements for plans and issuers regarding disclosures to participants, beneficiaries, and enrollees describing the Federal external review procedures (including the right to file a request for an external review of an adverse benefit determination or a final internal adverse benefit determination in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees.

(vii) These standards will require plans and issuers to provide information relevant to the processing of the external review, including, but not limited to, the information considered and relied on in making the adverse benefit determination or final internal adverse benefit determination.

(e) *Form and manner of notice—*(1) *Group health coverage—*(i) For purposes of this section, a group health plan and health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner—

(A) For a plan that covers fewer than 100 participants at the beginning of a plan year, if the plan and issuer provide notices upon request in a non-English language in which 25 percent or more of all plan participants are literate only in the same non-English language; or

(B) For a plan that covers 100 or more participants at the beginning of a plan year, if the plan and issuer provides notices upon request in a non-English language in which the lesser of 500 or more participants, or 10 percent or more of all plan participants, are literate only in the same non-English language.

(ii) If an applicable threshold described in paragraph (e)(1)(i) of this section is met, the plan and issuer must also—

(A) 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;

(B) Once a request has been made by a claimant, provide all subsequent notices to the claimant in the non-English language; and

(C) 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.

(2) *Individual health insurance coverage—*(i) For purposes of this section, a health insurance issuer offering individual health insurance coverage is considered to provide relevant notices in a culturally and linguistically appropriate manner if the issuer provides notices upon request in a non-English language in which 10 percent or more of the population residing in the claimant's county are literate only in the same non-English language, determined in guidance published by the Secretary of Health and Human Services.

(ii) If the threshold described in paragraph (e)(2)(i) of this section is met, the issuer must also—

(A) 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;

(B) Once a request has been made by a claimant, provide all subsequent notices to the claimant in the non-English language; and

(C) To the extent the issuer maintains a customer assistance process (such as a telephone hotline) that answers questions or provides assistance with filing claims and appeals, the issuer must provide such assistance in the non-English language.

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

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 147.140 of this part for

determining the application of this section to grandfathered health plans (providing that these rules regarding internal claims and appeals and external

review processes do not apply to grandfathered health plans).

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