U.S. Department of Labor Employee Benefits Security Administration
Washington, D.C. 20210

TECHNICAL RELEASE 2010-01

DATE: AUGUST 23, 2010

SUBJECT: INTERIM PROCEDURES FOR FEDERAL EXTERNAL REVIEW RELATING TO INTERNAL CLAIMS AND APPEALS AND EXTERNAL REVIEW UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

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 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 Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) have been issuing regulations in several phases to implement the revised PHS Act sections 2701 through 2719A and related provisions of the Affordable Care Act.

Section 2719 of the PHS Act applies to group health plans and health insurance coverage that are not grandfathered health plans within the meaning of section 1251 of the Affordable Care Act.[1] It sets forth standards for plans and issuers regarding both internal claims and appeals and external review. The Departments published interim final regulations implementing PHS Act section 2719 on July 23, 2010, at 75 FR 43330 (the interim final regulations). In general, the interim final regulations require plans and issuers to comply with the requirements of 29 CFR 2560.503-1 (the DOL claims procedure regulation) and impose specified additional standards for internal claims and appeals.

DISCUSSION:

Section 2719 of the PHS Act provides that plans and issuers in States without an applicable State external review process shall implement an effective external review process that meets minimum standards established by the Secretary through guidance and that is similar to a State external review process described in PHS Act Section 2719(b)(1). The statute and the interim final regulations also provide a basis for determining when plans and issuers must comply with

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

an applicable State external review process and when they must comply with the Federal external review process. Generally, if a State has an external review process that meets, at a minimum, the consumer protections set forth in the interim final regulations, an issuer (or a plan) subject to the State process must comply with the State process. The regulations include a transition period for plan years (in the individual market, policy years) beginning before July 1, 2011, during which the Department of HHS 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 is to apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

The preamble to the interim final regulations provided that the Departments would issue additional guidance on the Federal external review process. This technical release provides guidance on the interim Federal external review process for self-insured group health plans.

CONCLUSION:

This technical release sets forth an interim enforcement safe harbor for non-grandfathered self-insured group health plans not subject to a State external review process, and therefore subject to the Federal external review process. (In the case of health insurance coverage offered in connection with a group health plan, the health insurance issuer has primary responsibility to comply with the interim final regulations.) This interim enforcement safe harbor applies for plan years beginning on or after September 23, 2010 and until superseded by future guidance on the Federal external review process that is being developed and that will apply after this interim period. During the period that this interim enforcement safe harbor is in effect, the Department and the Internal Revenue Service[2] will not take any enforcement action against a group health plan that complies with either of the following interim compliance methods (and if a plan complies with one of the interim compliance methods of this technical release, no excise tax liability should be reported on IRS Form 8928 with respect to PHS Act section 2719(b)):

- Compliance with this technical release. The Department and the Internal Revenue Service will not take enforcement action against any plan that complies with the procedures set forth in this technical release. These procedures are based on the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners (NAIC Model Act) and in place on July 23, 2010.[3]

[2] In the notice published in the Federal Register, the Internal Revenue Service provided that it will not take any enforcement action with respect to PHS Act section 2719(b) against a self-insured group health plan that complies with the enforcement safe harbor described in this technical release.

[3] Even though these procedures are based on the NAIC Model Act, they do not include all the consumer protections of the NAIC Model Act. For example, the procedures set forth in this notice do not include the special provisions for claims relating to experimental or investigational treatment and do not include a

- Voluntary compliance with State external review processes. Alternatively, States may choose to expand access to their State external review process to plans that are not subject to the applicable State laws such as self-insured plans, and such plans may choose to voluntarily comply with the provisions of that State external review process. In such circumstances, while the interim enforcement safe harbor is in effect, the Department and the Internal Revenue Service also will not take enforcement action against a plan that voluntarily complies with the provisions of a State external review process that would not otherwise be applicable or available.

For purposes of this technical release, the definitions contained in the interim final regulations under PHS Act section 2719 apply. More guidance will be issued in the future on the standards for the Federal external review process that will apply after the interim enforcement safe harbor period.

A. Standard external review for self-insured group health plans

This section sets forth procedures for standard external review for self-insured group health plans. Standard external review is external review that is not considered expedited (as described in paragraph B of this section).

1. Request for external review. A group health plan must allow a claimant to file a request for an external review with the plan if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

2. Preliminary review. Within five business days following the date of receipt of the external review request, the group health plan must complete a preliminary review of the request to determine whether:

(a) The claimant is or was covered under the plan at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan at the time the health care item or service was provided;

(b) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan (e.g., worker classification or similar determination);

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government agency certifying and assigning independent review organizations. The NAIC Model Act is available at http://www.dol.gov/ebsa. Future guidance will address the minimum consumer protections required under the Federal external review process after the interim enforcement safe harbor period.

(c) The claimant has exhausted the plan's internal appeal process unless the claimant is not required to exhaust the internal appeals process under the interim final regulations; and

(d) The claimant has provided all the information and forms required to process an external review.

Within one business day after completion of the preliminary review, the plan must issue a notification in writing to the claimant[4]. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and contact information for the Employee Benefits Security Administration (toll-free number 866-444-EBSA (3272)). If the request is not complete, such notification must describe the information or materials needed to make the request complete and the plan must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

3. Referral to Independent Review Organization. The group health plan must assign an independent review organization (IRO) that is accredited by URAC or by a similar nationally-recognized accrediting organization to conduct the external review. Moreover, the plan must take action against bias and to ensure independence. Accordingly, plans must contract with at least three (3) IROs for assignments under the plan and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection). In addition, the IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

A contract between a plan and an IRO must provide the following:

(a) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan.

(b) The assigned IRO will timely notify the claimant in writing of the request's eligibility and acceptance for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO within ten business days following the date of receipt of the notice additional information that the IRO must consider when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(c) Within five business days after the date of assignment of the IRO, the plan must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan to timely provide the documents and information must not delay the conduct of the external review. If the plan fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to

[4] Note that, under the interim final regulations, any reference to a "claimant" includes the claimant's authorized representative. See 29 CFR 2590.715-2719(a)(2)(iii).

reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(d) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan. Upon receipt of any such information, the plan may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan.

(e) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's internal claims and appeals process applicable under paragraph (b) of the interim final regulations under section 2719 of the PHS Act. In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(i) The claimant's medical records;

(ii) The attending health care professional's recommendation;

(iii) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(iv) The terms of the claimant's plan to ensure that the IRO's decision is not contrary to the terms of the plan, unless the terms are inconsistent with applicable law;

(v) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(vi) Any applicable clinical review criteria developed and used by the plan, unless the criteria are inconsistent with the terms of the plan or with applicable law; and

(vii) The opinion of the IRO's clinical reviewer or reviewers after considering the information described in this notice to the extent the information or documents are available and the clinical reviewer or reviewers consider appropriate.

(f) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of final external review decision to the claimant and the plan.

(g) The assigned IRO's decision notice will contain:

(i) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the previous denial);

(ii) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(iii) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(iv) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(v) A statement that the determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or to the claimant;

(vi) A statement that judicial review may be available to the claimant; and

(vii) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(h) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

4. Reversal of plan's decision. Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final internal adverse benefit determination, the plan immediately must provide coverage or payment (including immediately authorizing or immediately paying benefits) for the claim.

B. Expedited external review for self-insured group health plans

1. Request for expedited external review. A group health plan must allow a claimant to make a request for an expedited external review with the plan at the time the claimant receives:

(a) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under the interim final regulations would seriously jeopardize

the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

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

2. Preliminary review. Immediately upon receipt of the request for expedited external review, the plan must determine whether the request meets the reviewability requirements set forth in paragraph A.2 above for standard external review. The plan must immediately send a notice that meets the requirements set forth in paragraph A.2 above for standard external review to the claimant of its eligibility determination.

3. Referral to independent review organization. Upon a determination that a request is eligible for external review following the preliminary review, the plan will assign an IRO pursuant to the requirements set forth in paragraph A.3 above for standard review. The plan must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's internal claims and appeals process.

4. Notice of final external review decision. The plan's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph A.3 above, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan.

PAPERWORK REDUCTION ACT:

According to the Paperwork Reduction Act of 1995 (Pub. L. 104-13) (PRA), no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The Department notes that a Federal agency cannot conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond

to a collection of information unless it displays a currently valid OMB control number. *See* 44 U.S.C. 3507. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number. *See* 44 U.S.C. 3512.

This guidance revises the information collection request (ICR) titled the "Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Plans," which was approved by OMB on July 19, 2010, under OMB control numbers 1210-0144. OMB has approved the revision to the ICR contained in this notice pursuant to the emergency review procedures under 5 CFR 1320.13. The Department estimates that the public hour burden associated with complying with the Federal external review procedures will be 25 minutes and the cost burden will be approximately $9 for each external appeal conducted. A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW, Room N-5718, Washington, DC 20210. Telephone: (202) 693-8410; Fax: (202) 219-4745. These are not toll-free numbers. E-mail: ebsa.opr@dol.gov. ICRs submitted to OMB also are available at reginfo.gov (http://www.reginfo.gov/public/do/ PRAMain).

Interested parties are encouraged to send comments regarding the burden estimate or any other aspect of this revision to the ICR, including suggestions for reducing this burden, to the U.S. Department of Labor, Office of the Chief Information Officer, Attention: Departmental Clearance Officer, 200 Constitution Avenue, N.W., Room N-1301, Washington, DC 20210 or email DOL_PRA_PUBLIC@dol.gov and reference the OMB Control Number 1210-0144.

Questions concerning the information contained in this technical release may be directed to the Office of Health Plan Standards and Compliance Assistance at 202-693-8335.