

Technical Release No. 2011-02

Guidance on External Review for Group Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage, and Guidance for States on State External Review Processes

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Background

The Patient Protection and Affordable Care Act, Public Law 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act, Public Law 111-152, was enacted on March 30, 2010 (collectively known as the "Affordable Care Act"). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers offering group and individual health insurance coverage. 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 Health and Human Services (HHS), Labor, and the Treasury (collectively referred to as the Departments) have been issuing regulations in several phases to implement the revised sections 2701 through 2719A of the PHS Act and related provisions of the Affordable Care Act. Section 2719 of the PHS Act applies to group health plans and health insurance issuers in the individual and group health insurance markets 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 process and external review. The Departments published interim final rules implementing section 2719 of the PHS Act on July 23, 2010, at 75 FR 43330 (the July 2010 regulations) and are issuing an amendment to those rules contemporaneously with this technical guidance.

Section 2719(b)(1) of the PHS Act requires that group health plans and health insurance issuers in the group and individual market comply with a State external review process if that process includes, at a minimum, the consumer protections set forth in the Uniform Health Carrier External Review Model Act issued by the National Association of Insurance Commissioners (the NAIC Uniform Model Act).⁽²⁾ Paragraph (c)(2) of the July 2010 regulations sets forth the 16 minimum consumer protection standards from the NAIC Uniform Model Act that a State external review process must include in order to be authorized under section 2719(b)(1) of the PHS Act.

Therefore, under previous guidance, for a State external review process to apply (or continue to apply) to health insurance issuers (and certain plans⁽³⁾) for plan years (in the individual market, policy years) beginning on or after July 1, 2011, the State process was required to include the 16 minimum consumer protection standards set forth in paragraph (c)(2) of the July 2010 regulations. These 16 minimum consumer protection standards are being amended, in limited respects, by an amendment to the July 2010 regulations that is being issued contemporaneously with this technical guidance. That amendment to the July 2010 regulations also modifies (as described below) the transition period described in the first sentence of this paragraph.

These 16 minimum consumer protection standards, as amended, may be summarized as follows:⁽⁴⁾

1. The process must provide for external review of adverse benefit determinations (and final internal adverse benefit determinations) based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.
2. Issuers (or plans) must be required to provide effective written notice to claimants of their rights to

external review.

3. If exhaustion of internal appeals is required prior to external review, exhaustion must be unnecessary if – (a) the issuer (or plan) waives the exhaustion requirement; (b) the issuer (or plan) is considered to have exhausted the internal appeals process by failing to comply with the requirements of the internal appeals process except those failures that are based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant⁽⁵⁾; or (c) the claimant simultaneously requests an expedited internal appeal and an expedited external review.
4. The cost of an independent review organization (IRO) to conduct an external review must be borne by the issuer (or plan), although the process may require a nominal filing fee⁽⁶⁾ from the claimant requesting external review.
5. There cannot be any restriction on the minimum dollar amount of a claim in order to be eligible for external review.
6. The process must allow at least four months to file a request for external review after the receipt of the notice of adverse benefit determination or final internal adverse benefit determination.
7. The IRO must be assigned by the State or an independent entity, on a random basis or another method of assignment that ensures the independence and impartiality of the assignment process (such as rotational assignment), and in no event assigned by the issuer, the plan, or the individual.
8. The process must provide for the maintenance of a list of approved IROs (only those that are accredited by a nationally recognized private accrediting organization) qualified to conduct the external review based on the nature of the health care service that is the subject of the review.
9. Approved IROs must have no conflicts of interest that will influence their independence.
10. Claimants must be allowed to submit to the IRO additional information in writing that the IRO must consider when conducting the external review, and the claimant must be notified of the right to submit additional information to the IRO; the IRO must allow the claimant at least 5 business days to submit any additional information and any additional information submitted by the claimant must be forwarded to the issuer (or plan) within one business day of receipt by the IRO.
11. The IRO decision must be binding on the claimant, as well as the plan or issuer (except to the extent that other remedies are available under State or Federal law).⁽⁷⁾
12. For standard external review, the IRO must provide written notice to the issuer (or plan) and the claimant of its decision to uphold or reverse the adverse benefit determination within no more than 45 days after the receipt of the request for external review.
13. The process must provide for an expedited external review in certain circumstances and, in such cases, provide notice of the decision as expeditiously as possible, but not later than 72 hours after receipt of the request for external review (and if notice of the IRO's decision is not in writing, the IRO must provide written confirmation of its decision within 48 hours after the date of the notice of the decision).
14. Issuers (or plans) must provide a description of the external review process in or attached to the summary plan descriptions, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage provided to participants, beneficiaries, or enrollees, substantially similar to section 17 of the NAIC Uniform Model Act.
15. The IRO must maintain written records and make them available upon request to the State, substantially similar to section 15 of the NAIC Uniform Model Act.
16. The process must follow procedures for external reviews involving experimental or investigational treatment, substantially similar to section 10 of the NAIC Uniform Model Act.

Under section 2719(b)(2) of the PHS Act, if a State's external review process does not meet these minimum consumer protection standards, group health plans and health insurance issuers in the group and individual market in that State are required to implement an effective external review process that meets minimum standards established by the Secretary through guidance. These standards must be similar to the standards established under section 2719(b)(1) of the PHS Act and must meet the requirements set forth in paragraph (d) of the July 2010 regulations.

Accordingly, there may be external review processes authorized under PHS Act section 2719(b)(1) and paragraph (c) of the July 2010 regulations (hereinafter referred to as "NAIC-parallel processes") and there may be external review processes authorized under statutory PHS Act section 2719(b)(2) and paragraph (d) of the July 2010 regulations (hereinafter referred to as "NAIC-similar processes").

Discussion

A. Status of State External Review Implementation

The Departments understand that many States have been working to make changes to implement NAIC-parallel processes. HHS continues to evaluate State external review processes to determine whether they meet the standards for an NAIC-parallel process. If HHS determines that a State's external review process does not meet those minimum consumer protection standards, issuers (and plans) will need a reasonable opportunity to respond and change to a different process.

For these reasons, the Departments are establishing: (1) a transition period until January 1, 2012 for State external review process implementation; and (2) a set of temporary standards for NAIC-similar processes that will apply until January 1, 2014.

Transition period

In light of these circumstances, and in order to allow time for issuers (and plans) to make a reasonable transition to a different process, the Departments are modifying the transition period for States to implement external review processes.⁽⁸⁾ Specifically, under an amendment to the July 2010 regulations being published contemporaneously with this technical guidance, the transition period is modified to extend through December 31, 2011. As discussed below, HHS intends to issue determinations regarding State external review implementation no later than July 31, 2011.

Temporary standards for NAIC-similar consumer protections

In addition to the transition period, this technical guidance establishes minimum consumer protection standards for NAIC-similar processes that will temporarily apply for a State-administered external review process authorized under section 2719(b)(2) of the PHS Act and paragraph (d) of the July 2010 regulations. These temporary standards will apply to health insurance issuers (and, if applicable, self-insured nonfederal governmental plans) in a State until January 1, 2014.⁽⁹⁾

Until the earlier of these two dates, issuers (and plans) will comply with an applicable State external review process that meets these temporary standards even if it does not meet all the minimum consumer protections of paragraph (c)(2) of the July 2010 regulations, as amended. Beginning January 1, 2014, a State external review process will need to satisfy the standards of paragraph (c)(2) of the July 2010 regulations, as amended, or the issuer (or plan) will become subject to a Federally-administered external review process.

The temporary standards for a State-administered external review process to be considered an NAIC-similar process are all of the following:

1. The process must provide for external review of adverse benefit determinations (and final internal adverse benefit determinations) based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.⁽¹⁰⁾
2. The process provides for external review of adverse benefit determinations (and final internal adverse

benefit determinations) involving experimental or investigational treatments or services and must have at least all of the protections that are available for external reviews based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

3. Issuers (or plans) are required to provide effective written notice to claimants of their rights to external review in their summary plan descriptions and plan materials and on each notice of adverse benefit determination. These notice requirements may not be articulated in a State's external review statute but may be established in other areas of State law, rules, or procedures - for example, those that apply to internal appeals, claims payment practices, or other areas of State oversight.
4. If exhaustion of internal appeals is required prior to external review, exhaustion must be unnecessary if -- (a) the internal appeal process timelines are not met; or (b) in an urgent care situation, the claimant files for an external review without having exhausted the internal appeal process. These requirements may not be articulated in a State's external review statute but may be established in other areas of State law, rules, or procedures - for example, those that apply to internal appeals, claims payment practices, or other areas of State oversight.
5. The cost of an external review must be borne by the issuer (or plan), and the claimant cannot be charged a filing fee in excess of \$25 per external review.
6. There cannot be any restriction on the minimum dollar amount of a claim in order to be eligible for external review.
7. The claimant must have at least 60 days to file for external review after the receipt of the notice of adverse benefit determination or final internal adverse benefit determination.
8. The IRO must be assigned impartially. The claimant and issuer (or plan) should have no discretion as to the IRO that is chosen.
9. If the State contracts with, or otherwise identifies one or more IROs to provide external review, the State must have a process in place for quality assurance of IROs.
10. If the State contracts with, or otherwise identifies one or more IROs to conduct external reviews, the State must ensure conflict of interest protections on the part of the IRO when it participates in external review decisions.
11. The IRO decision is binding and must be enforceable by the State.
12. For standard external reviews (those not involving urgent care), the IRO must inform the issuer and the claimant, in writing, of its decision within 60 days from receipt of the request for external review.
13. The process must provide for expedited external review of urgent care claims. In such cases, the IRO must inform the issuer and the claimant of an urgent care decision within four business days or less (depending on medical exigencies of the case) from receipt of the request for review. If the IRO's decision was given orally, the IRO must provide written notice of its decision within 48 hours of the oral notification.

Determinations regarding individual State external review processes

Not later than July 31, 2011, HHS will determine whether each State external review process meets the standards for NAIC-parallel processes outlined in paragraph (c)(2) of the July 2010 regulations, as amended, or the standards for NAIC-similar processes outlined in this technical guidance. If a State process meets neither standard, health insurance issuers (and, if applicable, self-insured nonfederal governmental plans) in the State will be subject to a Federally-administered external review process (discussed further below). If a State believes that this determination is not accurate, the State may request, within 30 days of receiving its determination letter, that HHS re-evaluate the State's external review process. Additional instructions on redeterminations will be available in the initial determination letters. If a State does not request a re-determination, this initial determination will be considered a final determination. Final determinations will be in place no later than October 1, 2011, which gives plans and

issuers three months to transition to a different process, if warranted, by January 1, 2012. If, at any time after HHS makes a final determination, the State changes its external review process, the State may request a new determination.⁽¹¹⁾

Finally, in order to continue to be considered a NAIC-similar process under section 2719(b)(2) of the PHS Act and this technical guidance, States may not reduce the consumer protections in their external review process below the level that applies at the time HHS makes its finding. For example, if on or before July 31, 2011, HHS determines a State external review process is an NAIC-similar process and the State external review process allows consumers up to 120 days to file for external review, that protection cannot be narrowed later to allow consumers only up to 60 days to file for external review. If a State-administered process reduces consumer protections below the level that applies at the time HHS makes its finding, plans and issuers in the State will be required to participate in a Federally-administered external review process.

B. Federal External Review Processes

Since publication of the July 2010 regulations, the Departments have issued several technical guidance documents that set forth the Federally-administered external review process for specified types of health coverage.⁽¹²⁾ Certain aspects of this previous technical guidance are modified by this Technical Release 2011-02, as discussed below.

Health insurance issuers and self-insured nonfederal governmental plans

All self-insured nonfederal governmental health plans, as well as health insurance issuers in the group and individual market in States whose external review processes are found not to meet the requirements to be an NAIC-parallel process or an NAIC-similar process, must participate in a Federally-administered external review process. Such plans and issuers may choose to participate in the Federal external review process administered by HHS agreement through the Office of Personnel Management (the HHS-administered process) or engage in the private accredited IRO process for plans subject to ERISA and/or the Code. This includes issuers (and self-insured nonfederal governmental plans) in Alabama, Nebraska, Mississippi, U.S. Virgin Islands, Guam, American Samoa, and Northern Mariana Islands that are currently using the HHS-administered process.

Separate guidance published contemporaneously by HHS addresses how issuers and self-insured nonfederal governmental plans elect one of these two Federal external review processes.

Self-insured plans subject to ERISA and/or the Internal Revenue Code

On August 23, 2010, the Department of Labor issued Technical Release 2010-01 (T.R. 2010-01)⁽¹³⁾ setting forth an interim enforcement safe harbor regarding external review for self-insured plans subject to ERISA and/or the Code. In general, T.R. 2010-01 provided that the Department of Labor and the Internal Revenue Service (IRS) would not take enforcement action against a group health plan that either: (1) complied with the standards set forth in the technical release; or (2) voluntarily complied with a State external review process.

Among the standards set forth in T.R. 2010-01, plans were to contract with at least three accredited IROs and rotate assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection). Immediately after publication of that technical guidance, many plans and issuers indicated that they were experiencing difficulty contracting with three IROs. While many IROs indicated that they had capacity to handle the additional external reviews, it appeared they were experiencing difficulty responding to numerous requests to negotiate new contracts from multiple plans and their service providers in a brief period. Accordingly, on September 20, 2010, the Departments issued Affordable Care Act Implementation FAQs Part I.⁽¹⁴⁾ Among other things, these FAQs provided that, for plans that do not strictly comply with the enforcement safe harbor of T.R. 2010-01, compliance would be determined on a case-by-case basis. An example was given in FAQ-8 of a plan that had failed to contract with three IROs. The FAQ provided that the example was not a *per se* violation of PHS Act section 2719(b)

and that, instead, the plan could demonstrate other steps taken to ensure that its external review process was independent and without bias.

During the approximately nine months since publication of these FAQs, the marketplace for IROs has had an opportunity to adjust. Plans and IROs have had time to develop standard contractual documents, and many plans and issuers are using service providers such as third-party administrators (TPAs) to enter into global contracts, eliminating the need for each plan to have its own contract, and building economies of scale and contracting efficiencies into the process.⁽¹⁵⁾ At the same time, concerns have been identified about the potential for bias when large plans use only one IRO, since the IRO can become very dependent on the plan for its financial security.

Accordingly, in response to these concerns, and in recognition of the experience that has been gained in the past nine months, the Department of Labor and the IRS are modifying their enforcement policy with respect to IROs. Specifically, to be eligible for a safe harbor from enforcement from the Department of Labor and the IRS, self-insured plans will be required to contract with at least two IROs by January 1, 2012 and with at least three IROs by July 1, 2012 and to rotate assignments among them. These requirements remain part of an enforcement safe harbor, and a plan may use an alternative process to meet the standards of paragraph (d)(2)(i) of the July 2010 regulations regarding random assignment. However, the Department of Labor and the IRS will look closely at any process other than the rotational assignment referred to in T.R. 2010-01, and modified in this T.R. 2011-02 when making its case-by-case determinations. At a minimum, the Department of Labor and the IRS expect plans to document how any alternative process constitutes random assignment, as well as how it ensures that the process is independent (not subject to undue influence by the plan) and without bias.

C. Federal External Review Processes

Consistent with this technical guidance and the contemporaneous amendment to the July 2010 regulations, the Departments are also issuing a revised model notice of adverse benefit determination, a revised model notice of final internal adverse benefit determination, and a revised model notice of final external adverse benefit determination. These notices are included in the Appendix to this T.R. 2011-02.

The Department of the Treasury and the IRS have reviewed and concur with this Technical Release.

For Further Information Contact: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at 202-693-8335; and Ellen Kuhn, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301-492-4100.

Footnotes

1. The Departments published interim final regulations implementing section 1251 of the Affordable Care Act on June 17, 2010, at 75 FR 34538, and amended them on November 17, 2010 at 75 FR 70114.
2. The July 2010 regulations specify that the relevant NAIC Uniform Model Act is the version in place on July 23, 2010. This version of the NAIC Uniform Model Act is available at www.dol.gov/ebsa and cciio.cms.gov.
3. While the preemption provisions of ERISA ordinarily would prevent a State external review process from applying to most self-insured plans, the preamble to the July 2010 regulations states that a State external review process could apply to and be binding on a self-insured group health plan under some circumstances (e.g., nonfederal governmental plans not covered by ERISA preemption).
4. This list is intended only to summarize the consumer protection standards set forth at paragraph (c) (2) of the July 2010 regulations, as amended, not to make any substantive change to those standards. To the extent there is any difference between the standards summarized in this Technical Release and the standards set forth in the July 2010 regulations, as amended, the standards set forth in the July 2010 regulations control.

5. The amendment to the July 2010 regulations issued contemporaneously with this Technical Release adds a new paragraph (b)(2)(ii)(F)(2) to reflect an exception to the strict compliance standard for certain de minimis violations. The effect of this amendment on the standard set forth in paragraph (c)(2)(iii) is shown here for completeness; however, paragraph (c)(2)(iii) itself has not been amended.
6. For this purpose, to be considered nominal, a filing fee must not exceed \$25, must be refunded to the claimant if the adverse benefit determination or final internal adverse benefit determination is reversed through external review, must be waived if it 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.
7. The amendment to the July 2010 regulations issued contemporaneously with this Technical Release clarifies that the requirement that the decision be binding does not preclude a plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. In addition, the amendment clarifies that a plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.
8. The Departments acknowledge that some States have enacted consumer protections beyond those in operation on the date the Affordable Care Act was enacted. Of course, those later-added consumer protections will generally apply to coverage in such States, in accordance with ERISA section 731 and PHS Act section 2724.
9. Of course, if a State enacts an NAIC-parallel law prior to January 1, 2014, coverage subject to that State law will be required to comply with the provisions of that State law, in accordance with ERISA section 731 and PHS Act section 2724.
10. The amendment to the July 2010 regulations issued contemporaneously with this technical release sets forth temporary modifications to the scope of claims eligible for review under a Federal external review process, except to the extent the Departments determine otherwise through guidance. Because this modified Federal scope is broader than the scope of external review required by the NAIC Uniform Model Act, and the Departments expects that States that are temporarily operating an external review process under Federal standards (the States with NAIC-similar processes) are working on implementing the minimum consumer protections of paragraph (c)(2) of the July 2010 regulations, the Departments determine that the scope of external review under the temporary standards in such States will equal the scope of external review under the NAIC Uniform Model Act. That is, in States where HHS determines a temporary process authorized under section 2719(b)(2) of the PHS Act may operate under Federal standards before 2014, the scope of adverse benefit determinations eligible for external review must include decisions 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.
11. Future guidance will address compliance dates for issuers (and, if applicable, nonfederal governmental plans) if a State changes its external review process and requests a new determination.
12. In any case, if a State external review process applies to and is binding on a health insurance issuer of an insured group health plan, including an insured ERISA plan, under paragraph (c) of the July 2010 regulations (regarding State standards for external review), as amended, then it is the issuer, not the insured group health plan, that is required to provide an external review process (by complying with either the State external review process or the Federal external review process).
13. T.R. 2010-01 is available at <http://www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf>.
14. Part I of the Affordable Care Act Implementation FAQs is available at available at <http://www.dol.gov/ebsa/faqs/faq-aca.html> and

http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs.html#claims.

15. FAQ-9, issued as part of the same guidance package, recognized that plans are not required to contract directly with IROs and may, instead, rely on contracts with TPAs. That FAQ guidance is not modified in any way by this technical release.

Appendix

- [Revised Model Notice of Adverse Benefit Determination](#)
- [Revised Model Notice of Final Internal Adverse Benefit Determination](#)
- [Revised Model Notice of Final External Review Decision](#)