DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

TECHNICAL GUIDANCE- January 11, 2017

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Subject: Standards for Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage Using the HHS-Administered Federal External Review Process

Summary of Updates: This Technical Release replaces the technical guidance issued June 22, 2011[1] with standards adopted in the final regulation at 76 FR 37208 that further define requirements under Public Health Service Act (PHS Act) section 2719(b)(1). Since the June 22, 2011 technical guidance was issued, MAXIMUS (a Federal contractor) has started conducting the HHS-Administered Federal external review process, which previously was conducted by the Office of Personnel Management (OPM). This Technical Release outlines the requirements for group health plans and health insurance issuers that are subject to the HHS-Administered Federal external review process under section 2719(b)(2) of the PHS Act.

I. Background

Section 2719(b)(1) of the PHS Act requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual coverage comply with the applicable State external review process in their State if that process includes, at a minimum, the consumer protections set forth in the Uniform External Review Model Act issued by the National Association of Insurance Commissioners ("NAIC Uniform Model Act") and is binding on the plan or issuer. If the State external review process does not meet this standard, or if the plan or issuer is not subject to State insurance regulation, section 2719(b)(2) of the PHS Act provides that group health plans and health insurance issuers 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 that meets the standards in section 2719(b)(1) of the PHS Act.[2] The regulations at 45 CFR 147.136(d) describe a process for meeting this requirement, referred to as the Federal external review process.[3]

[1] The previously issued technical guidance was: Technical Guidance for Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review for Health Insurance Issuers in the Group and Individual Markets under the Patient Protection and Affordable Care Act.

[2] Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum consumer protections set forth in the NAIC Uniform External Review Model Act if the State process meets the NAIC-similar standards (See Technical Release 2011-02, available here: https://www.cms.gov/CCIIO/Resources/Files/Downloads/appeals_srg_update.pdf). Once this transition period has ended, plans and issuers in a State that has not implemented NAIC-parallel standards must comply with a Federal external review process.

[3] Please note that in cases where health insurance coverage is offered in connection with a group health plan, the obligation to comply with an external review process is satisfied for both the plan and the issuer if either the plan or issuer complies with the Federal external review process or with the State external review process, as applicable (45 CFR 147.136(b)(2)).

Insured coverage not subject to an applicable State external review process under 45 CFR 147.136(c) and self-insured non-Federal governmental plans may elect to use the Federal Independent Review Organization (IRO) external review process as set forth in 45 CFR 147.136(d)(2) or the HHS-administered Federal external review process as set forth in 45 CFR 147.136(d)(4) and outlined in the following guidance.[4]

II. HHS-Administered Federal External Review Process for Self-Insured Non-Federal Governmental Health Plans and Health Insurance Issuers in the Group and Individual Markets

External review is available for enrollees in non-grandfathered individual health insurance coverage and participants and beneficiaries in non-grandfathered group health plans. Consistent with the scope specified in 45 CFR 147.136(d)(1)(i)(A) for the Federal IRO external review process, the HHS-administered Federal external review process is available for adverse benefit determinations (including final internal adverse benefit determinations) by a plan or issuer that involve medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and 26 CFR 54.9812, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer, as well as any rescission of coverage. External review is not available for participants and beneficiaries in group health plans to resolve disputes about eligibility to participate in the group health plan, other than those disputes that are related to rescissions.

A. Procedures for providing standard external review under the HHS-administered Federal external review process.

This section sets forth the requirements for a standard external review under the HHS-administered Federal external review process. Standard external review is external review for adverse benefit determinations and final internal adverse benefit determinations that do not meet the criteria for expedited review (as described in Section B of this guidance).

1. Request for external review. A claimant or authorized representative ("claimant") may file a written request for an external review with the external review examiner ("examiner") 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,

[4] Self-insured group health plans that are not non-Federal governmental plans must use the Federal IRO external review process (as set forth in 45 CFR 147.136(d)(2)).

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. Notice to claimants. An adverse benefit determination or a final internal adverse benefit determination must contain a notice to the claimant that the claimant can request an external review of the adverse benefit determination or final internal adverse benefit determination. The notice must meet all of the requirements contained in 45 CFR 147.136(b)(2)(ii)(E) and 147.136(b)(3)(ii)(E), as applicable. Among these requirements, the notice must inform the claimant that the claimant can request an external review in writing by faxing their request to 1-888-866-6190, or by sending it by mail to: MAXIMUS Federal Services, 3750 Monroe Avenue, Suite 705, Pittsford, NY 14534. In addition, the notice must inform the claimant that if the claimant has any questions or concerns during the external review process, the claimant can call the toll-free number 1-888-866-6205, and that the claimant can submit additional written comments to the external reviewer at the mailing address above. The claimant also must be notified that if any additional information is submitted, it will be shared with the plan or issuer to give the plan or issuer an opportunity to reconsider the denial. Lastly, plans and issuers must provide claimants with the Privacy Act Statement. This Statement can be downloaded at https://www.cms.gov/cciio/Resources/forms-reports-and-other-resources/index.html. Self-insured, non-Federal governmental plans and issuers using the HHS-administered external review process must electronically provide to HHS samples of each of their notices that contain this information. The samples should be submitted at externalappeals@cms.hhs.gov. If these notices are changed during the plan or policy year, updated copies must be sent electronically to HHS at externalappeals@cms.hhs.gov.

3. Independent Review Organization qualifications. The external review will be referred to an Independent Review Organization (IRO) that is accredited by a nationally-recognized accrediting organization. The IRO referral process must provide for the following:

   a. The plan or issuer must ensure that the IRO process is not biased and ensures independence;

   b. The plan or issuer must contract with at least three IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

   c. The plan or issuer must not offer or provide any financial incentives based on the likelihood that the IRO will support the denial of benefits.

   d. The plan or issuer may not impose, and must ensure that the IRO

does not impose, any costs, including filing fees, on the claimant requesting the external review.

4. Independent reviewer qualifications. The external review will be conducted by an independent third party with clinical and legal expertise and with no financial or personal conflicts with the plan or issuer. This individual is referred to as the examiner.

5. Procedure for preliminary review. When the examiner receives an external review request, the examiner will contact the plan or issuer.

   a. Within five business days of receipt of request by the examiner, the plan or issuer must provide to the examiner all of the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination including:

      i. The claimant's certificate of coverage or benefit;

      ii. A copy of the adverse benefit determination;

      iii. A copy of the final internal adverse benefit determination, if applicable;

      iv. A summary of the claim;

      v. An explanation of the plan's or issuer's adverse benefit determination and final internal adverse benefit determination, if applicable; and

      vi. All documents and information considered in making the adverse benefit determination or final internal adverse benefit determination, including any additional information that may have been provided to the plan or issuer or relied upon by the plan or issuer during the internal appeals process.

      vii. This information can be faxed to 1-888-866-6190 or sent by priority mail to the mailing address listed in paragraph (A)(2) of this guidance.

   b. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may reverse the adverse benefit determination or final internal adverse benefit determination and conclude the external review.

   c. The examiner will review the information from the plan or issuer and may request additional information that it deems necessary for the external review. If the examiner requests additional information, the plan or issuer shall supply the information within five business days.

   d. If the examiner determines that the claimant is not eligible for an external appeal, the examiner will notify the claimant and the plan or issuer in writing.

6. Review process.

a. The examiner will review all of the information and documents that are timely received. In reaching a decision, the examiner will review the claim de novo and not be bound by any decisions or conclusions reached during the plan or issuer's internal claims and appeals process applicable under paragraph (b) of the regulations under section 2719 of the PHS Act.

b. The examiner will forward to the plan or issuer all documents submitted directly to the examiner by the claimant within one business day of receiving the documents. Upon receipt of this information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan or issuer 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 a decision to reverse its previous denial, the plan or issuer must provide written notice of its decision to the claimant and the examiner. The examiner must terminate the external review upon receipt of the notice from the plan or issuer.

c. The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider sources such as 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 or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

v. Appropriate evidence-based clinical practice guidelines, including guidelines developed by the Federal government or national professional medical societies, boards, or associations;

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

vii. To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

d. The examiner must provide written notice of the final external review decision as expeditiously as possible, but no later than 45 days after the examiner receives the request for the external review. The examiner must deliver the notice of final external review decision to the claimant and the plan or issuer.

e. The examiner's written notice of the final external review decision must contain the following:

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), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

ii. The date the examiner received the assignment to conduct the external review and the date of the examiner's decision;

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

iv. A discussion of the principal reason or reasons for the examiner's decision, including the rationale for the decision and any evidence-based standards that were relied on in making the 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 plan or issuer, or to the claimant, or to the extent the plan or issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that either denies the claim or otherwise fails to require such payment or benefits;

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.

f. After a final external review decision, the examiner must

maintain records of all claims and notices associated with the external review process for six years. The examiner must make such records available for examination by the claimant or plan or issuer upon request, except where such disclosure would violate State or Federal privacy laws.

7. Reversal of a plan's or issuer'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 or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

B. Procedures for providing expedited external review under the HHS-administered Federal external review process

This section sets forth the requirements for an expedited external review under the HHS- administered Federal external review process.

1. Request for expedited external review—A claimant may make a written or oral request for an expedited external review with the examiner at the time the claimant receives:
   a. An adverse benefit determination if the adverse bene fit determination involves a claimant's medical condition for which the timeframe for completion of an expedited internal appeal under the regulations at 45 CFR 147.136(b) would seriously jeopardize the claimant's life or health 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 claimant's life or health 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 the claimant has not been discharged from the facility.
2. Notice to claimants. An adverse benefit determination or a final internal adverse benefit determination must contain a notice to the claimant as set forth in paragraph (A)(2). In addition, claimants must be notified that in urgent care situations, their requests for expedited review can be initiated by calling the toll free number 1-888-866-6205.
3. Independent reviewer qualifications. The external review will be conducted by an independent third party that meets the requirements in paragraph (A)(3).
4. Procedure for preliminary review. When the examiner receives a request for an expedited external review request, the examiner will contact the plan or issuer.

a. Immediately upon receipt of request by the examiner, the plan or issuer must provide to the examiner all documents and other information required under paragraph (A)(4).

b. The examiner will review the information from the plan or issuer and may request additional information that it deems necessary to the external review.

c. If the examiner determines that the claimant is not eligible for expedited external appeal, the examiner will notify the claimant and the plan or issuer as expeditiously as possible.

5. Review process.

a. The examiner must comply with the requirements set forth in paragraph (A)(5)(a).

b. Upon receipt of any information submitted by the claimant, the examiner must immediately forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan or issuer decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide full coverage or payment. Immediately after reversing the decision, the plan or issuer must provide notice of its decision to the claimant and the assigned examiner. This notice can be provided orally but must be followed up with written notice within 48 hours. The examiner must terminate the external review upon receipt of the initial notice from the plan or issuer.

c. The examiner must provide notice of the final external review decision as expeditiously as the claimant's medical conditions or circumstances require, but in no event more than 72 hours after the examiner receives a request for an expedited external review. The examiner must deliver the notice of the final external review decision to the claimant and the plan or issuer. This notice can be initially provided orally but must be followed by a written notice within 48 hours.

d. The examiner's final external review decision notice must comply with the requirements set forth in paragraph (A)(5)(d).

e. After a final external review decision, the examiner must maintain records as required in paragraph (A)(5)(e).

6. Reversal of plan's or issuer's decision. The plan or issuer must comply with the requirements established in paragraph (A)(6).