Pursuant to the U.S. Office of Personnel Management’s (“OPM”) Multi-State Plan Program regulation at 45 C.F.R. § 800.503, OPM administers the External Review Process for disputed adverse benefit determinations submitted by enrollees in Multi-State Plan (“MSP”) health insurance options. This MSP Program Administration Letter sets forth the standards and timeframes that apply to requests for external review by enrollees in MSP coverage, together with an explanation of OPM’s rationales for determining these criteria. A summary MSP Program External Review Process standards sheet is attached.

In determining the MSP Program External Review Process standards, OPM analyzed section 2719 of the Public Health Service (“PHS”) Act and the NAIC Uniform External Review Model Act (April 2010) that is incorporated by reference into section 2719.1

OPM also reviewed the 16 minimum State external review standards set forth in regulations promulgated by the Departments of Health and Human Services (“HHS”), Labor, and Treasury (the “Tri-Departments”) at 45 C.F.R. § 147.136(c) to implement PHS Act section 2719(b)(1) (together with corresponding sections of the Employee Retirement Income Security Act and the Internal Revenue Code). In connection with these 16 minimum standards, OPM researched State laws and regulations in the 40 States (and the District of Columbia) where a State external review process presently applies.

The Tri-Departments regulation at 45 C.F.R. § 147.136(d) describes a Federal external review process for plans and issuers not subject to State standards. This Administration Letter has additionally been informed by the following subregulatory guidance, through which the Tri-Departments have facilitated a transition into compliance for plans and issuers:

- *Technical Guidance for Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review For Health Insurance Issuers in the*
HHS used this guidance to establish a Federal external review process that satisfies 45 C.F.R. § 147.136(d) and facilitates binding review by an independent review organization (IRO), that plans and issuers may use at no cost. This Federal process is administered by HHS through OPM, pursuant to an interagency agreement with HHS, under contract with Maximus Federal Services, Inc. to serve as the IRO (the “HHS-administered Federal Process”).

As clarified by HHS in its Technical Amendment Relating to OPM Multi-State Plan Program and External Review, finalized at 78 Fed. Reg. 68296 (November 13, 2013), the MSP Program External Review Process must meet the minimum requirements of the Federal external review process at 2719(b)(2) and 45 C.F.R. § 147.136(d), and may have a scope that exceeds these requirements.

In establishing these standards, OPM's aim is for the MSP Program External Review Process to be at least as protective to consumers as the processes applicable to issuers under otherwise applicable State or Federal external review processes, and therefore OPM's MSP Program External Review Process has exceeded minimum requirements for Federal external review in certain instances.

1. Scope

2 Available at: [http://www.cms.gov/CCIIO/Resources/Files/Downloads/interim_appeals_guidance.pdf](http://www.cms.gov/CCIIO/Resources/Files/Downloads/interim_appeals_guidance.pdf) (August 26, 2010). This Interim Guidance established a temporary, interim Federal process established by HHS and administered by OPM (pursuant to interagency agreement with HHS) through contract with Maximus Federal Services, Inc., that issuers and plans could rely upon during a period prior to July 1, 2011 while states were transitioning their external review process to become compliant with HHS minimum standards.


4 Available at: [http://www.cms.gov/CCIIO/Resources/Files/Downloads/appeals_srg_update.pdf](http://www.cms.gov/CCIIO/Resources/Files/Downloads/appeals_srg_update.pdf) (June 22, 2011). Technical Release 2011-02 established an alternative series of standards that issuers and plans could rely upon even though a State might not fully comply with the HHS minimum State standards by July 1, 2011, and extended the transition period for reliance on these alternative standards to January 1, 2012. It also explained a DOL safe harbor process for satisfying the Federal process by engaging at least three IROs and rotating assignments among them.
Similar to the disputed claims process administered by OPM under the Federal Employees Health Benefits (FEHB) Program, the MSP Program External Review Process encompasses disputed claims based on medical judgments as well as those based on non-medical judgment contract coverage. Thus, we explained in the preamble to the MSP Program final rule that “in addition to engaging an [IRO] for final, binding decisions” on MSP claims disputes “involving medical judgments, we have designed the external review process for the [MSP Program] to accommodate final, binding decisions by OPM on claims disputes involving interpretation of contract coverage that does not involve medical judgments.” *See 45 C.F.R. § 800.503(a).*

As indicated in the Tri-Department regulations, medical judgments include but are not limited to “those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; or its determination that a treatment is experimental or investigational.” *See 45 C.F.R. § 147.136(d)(1)(ii)(A).*

In general, the MSP Program External Review Process will apply to a denial of one or more specific claims under MSP coverage. However, any rescission of coverage, as described at 45 C.F.R. § 147.128, is subject to this external review process, regardless of whether the rescission involves denials of one or more specific claims. OPM will determine whether a specific claim or rescission is based on a medical judgment or an interpretation of contract coverage that does not involve medical judgment.

2. Notice

The minimum State standards set forth in the Tri-Department regulations at 45 C.F.R. § 147.136(c)(2)(ii) require that issuers “provide effective written notice to [enrollees] of their rights in connection with an external review for an adverse benefit determination.”

The Interim Guidance clarifies that notices under the HHS-administered Federal process must include at least the following elements: (1) a statement of the enrollee’s right to external review, (2) a statement of the enrollee’s right to submit additional information (which will be shared with the issuer), and (3) a Privacy Act statement. Technical Release 2011-02 attached a model notice, illustrating compliance with this requirement.

At a minimum, notices concerning MSP external review must include the three elements set forth in the Interim Guidance. In addition, notices must include contact information for OPM, appropriate State regulators, and consumer assistance programs or ombudsmen’s offices available to the enrollee.

In addition, the Tri-Department regulations establish standards for cultural and linguistic appropriateness. OPM adopted those standards in the MSP Program final rule at 45 C.F.R. § 800.503(b). Several States impose notice standards addressing cultural and linguistic appropriateness, accessibility and clarity, and assistance for individuals with limited English proficiency or literacy. The preamble to the MSP Program final rule expressly contemplates that

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MSP issuers will comply with such State laws and State requirements for form review. The preamble indicates that OPM additionally intends to review forms. Notices advising enrollees of external review rights should comply with State requirements, and OPM will work with State regulators to ensure that MSP issuers provide enrollees with appropriate notices.

3. Exhaustion of internal appeals processes

Neither the Interim Guidance nor Technical Release 2011-02 addresses exhaustion of internal appeals, except to permit non-exhaustion in the case of expedited external review. State laws are relatively uniform in requiring enrollees to exhaust any applicable internal appeals process, with some exceptions. The Tri-Department regulations (45 C.F.R. § 147.136(c)(2)(iii)) require that “[t]o the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer . . . has waived the requirement, the issuer . . . 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 . . .), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.” The MSP Program External Review Process will require exhaustion of internal remedies, subject to the exceptions laid out in section 147.136(c)(2)(iii) of the Tri-Department regulations.

4. Cost of review

Enrollees seeking external review through the HHS-administered Federal process do not have to pay a filing fee. State processes may include “nominal” filing fees that may not be more than $25, may not amount to more than $75 in any plan year, and must be refundable for meritorious requests for external review. Some State processes do not permit enrollees to be charged filing fees. MSP enrollees will not be charged a filing fee to use the MSP Program External Review Process.

5. Minimum dollar amount

The HHS-administered Federal process does not, and each State process must not, require that a claim be for a minimum dollar amount in order for the denial of the claim to be subject to the external review process. Similarly, the MSP Program External Review Process will not require a request for external review to involve a minimum dollar amount in order to be subject to the process.

6. Time to file

The HHS-administered Federal process allows enrollees to request external review up to 4 months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. Several States apply longer time periods, while others use a 180-day or 6-month timeframe, and one State uses one year. Two States do not impose time limits for enrollees to seek external review of denied claims.
OPM will apply a one-year time limit for the MSP Program External Review Process, but will allow exceptions where an enrollee in any State provides a reasonable justification to demonstrate that circumstances warrant external review more than one year after final denial. In the event that an enrollee in a State without a time limit files a request for external review more than one year after final denial, OPM will consider the absence of a State-imposed time limit to be a circumstance that warrants an exception to the one year time limit, and OPM will allow the belated external review.

7. Impartial assignment of IRO

The Tri-Departments' regulation (45 C.F.R. § 147.136(c)(vii)) for minimum State standards regarding IRO assignment requires that an IRO be assigned “by a State or an independent entity, on a random basis or another method of assignment that ensures the independence or impartiality of the assignment process (such as rotational assignment), and in no event assigned by the issuer, the plan, or the individual.”

The HHS-administered Federal process includes a single IRO, under contract with OPM, which resolves all external reviews. Technical Release 2011-02 provides plans and issuers not subject to an applicable State external review process with a choice of electing either the HHS-administered Federal process or a process for engaging private, accredited IRO external review. OPM intends to contract with one or more IROs to implement the MSP Program External Review Process. For each external review of a denial based on medical judgment, OPM will impartially assign an IRO to render a final, binding decision.

8. List of approved IROs

Both the Tri-Departments' regulatory State minimum standards (45 C.F.R. § 147.136(c)(2)(viii)) and Technical Release 2011-02 call for a “list of approved IROs” accredited by a nationally recognized private accrediting organization and with clinical and legal expertise to conduct external reviews.

Historically, OPM contracted with one or more IROs to assist in the resolution of disputed claims under the FEHB Program and under the Preexisting Condition Insurance Program (PCIP). OPM currently conducts external review using services of an IRO under the HHS-administered Federal process at 45 C.F.R. § 147.136(d) that is generally available to plans and issuers at no cost. The IRO qualifications for both the FEHB Program and PCIP disputed claims processes are substantially similar to those in the HHS-administered Federal process. OPM intends to select one or more IROs based on a similar set of qualifications and will publish those qualifications in a Request for Proposal (“RFP”).

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9. IRO conflicts of interest

Technical Release 2011-02 requires an IRO to be an independent third party with no financial or personal conflicts with the plan or issuer that will influence its independence. State laws and regulations generally prohibit conflicts of interest with varying degrees of specificity; no single State’s standard is obviously the most protective to consumers.

Under section 147.136(c)(2)(ix) of the Tri-Department regulations, a State process must provide that an approved 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.” Moreover, with respect to conflicts between a party and an individual within an IRO who is responsible for externally reviewing a case, “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;
- the enrollee (and any parties related to the enrollee) whose treatment is the subject of external review;
- any officer, director, or management employee of the issuer;
- the health care provider or that provider’s group or the practice association recommending the treatment in question;
- the facility where the recommended treatment would be provided; or
- the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

For purposes of the MSP Program External Review Process, OPM will use the same criteria for defining prohibited conflicts of interest as in the Tri-Department regulations.

10. Additional information

The Tri-Department regulations (45 C.F.R. § 147.136(c)(2)(x)) require that applicable State processes permit enrollees to submit additional information within at least 5 business days after receiving notice of the right to submit additional information. Several States permit enrollees to submit additional information within a longer period, as long as 15 business days or 20 calendar days. The FEHB Program disputed claims process conducted by OPM permits FEHB enrollees to submit additional information at any point until a final decision is made, which, in practice, usually occurs within 60 calendar days.

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7 State laws vary in the use of business days or calendar days. To promote consistency and predictability, timeframes under the MSP Program External Review Process will be counted using calendar days.
OPM's goal in establishing these standards is to ensure that MSP enrollees have protections at least as strong as those available to other consumers in their State. OPM will therefore permit MSP enrollees to submit additional information for at least 20 calendar days after being notified of their right to submit additional information. In addition, OPM, in its sole discretion, reserves the right to accept additional information from enrollees beyond 20 days until a final decision is made.

This means that the period within which an MSP enrollee may submit additional information may affect the overall timeframe for OPM or an IRO to make a final decision on external review. Neither OPM nor an IRO can render a final decision as long as an opportunity to submit additional information remains open. See the discussion of Standard 12 below.

11. Decision is binding

Section 147.136(c)(2)(xi) of the Tri-Department regulations requires that an applicable State process “provide that the decision is binding on the . . . issuer, as well as the [enrollee], except to the extent other remedies are available under State or Federal law . . .,” except that the issuer may elect to reverse its denial whether or not the IRO upholds it upon external review. “For this purpose, the . . . issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the . . . issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.”

The Interim Guidance for the HHS-administered Federal process provides that “[u]pon receipt of a notice of a final external review decision reversing the adverse benefit determination or final internal adverse benefit determination, the health insurance issuer immediately must provide coverage or payment (including immediately authorizing or immediately paying benefits) for the claim.”

The Interim Guidance establishing the HHS-administered Federal process applies only to medical judgment denials and rescissions, and requires the IRO itself to send notice of the external review decision to the issuer and enrollee. The notice must include “[a] statement that the determination is binding except to the extent that other remedies may be available under State or Federal law . . . .” In Technical Release 2011-02, HHS articulated this standard by requiring that “[t]he IRO decision must be binding on the [enrollee], as well as the plan or issuer (except to the extent that other remedies are available under State or Federal law).”

Final external review decisions under the MSP Program External Review Process are binding on both the issuer and the enrollee, except to the extent that other remedies are available under Federal or State law. A final external review decision will be made by OPM for each external review not involving medical judgment, and will be made by an IRO for each external review involving strictly medical judgment. For external reviews that require determinations based on both medical judgment and interpretation of provisions of coverage, OPM will seek the opinion of an IRO regarding medical judgment questions, and will consider that opinion binding in rendering a final external review decision.
12. IRO decision within 45 days

For standard external review,8 the Tri-Department regulations (45 C.F.R. § 147.136(c)(2)(xii)) require a State process to include notice from an IRO to an enrollee of the external review decision within no more than 45 calendar days after the IRO received the enrollee’s request for external review. The HHS-administered Federal process requires the IRO’s decision within 45 days.

State laws diverge significantly with respect to this standard. Some State laws contemplate requests for external review to be submitted directly to an IRO, whereas others call for requests to be routed through the State Department of Insurance (“DOI”) or other regulatory authority before being submitted to an IRO. Some States’ timeframes are therefore specific to the amount of time an IRO may take to render a final decision, and others include time for the DOI to process a request and collect information. OPM, based on its research of current State standards, determined that the shortest period within which an IRO must render a final decision is 15 calendar days, and the fastest timeframe for an entire process that is routed through a regulatory agency is 30 calendar days.

For the MSP Program External Review Process to be meaningful to consumers, it must allow enough time for thorough information collection, development, and evaluation of each request for external review. As noted in the discussion of Standard 10, the opportunity for an MSP enrollee to submit additional information can have the effect of extending the timeframe for completing the entire external review process. OPM noted in the preamble to the MSP Program final rule that nearly all disputed claims under the FEHB Program are resolved within 60 calendar days, but a few require more time to reach the appropriate conclusion.

OPM recognizes the value of each type of timeframe to consumer protection; neither the regulatory agency nor the IRO should be allowed to delay rendering a final decision. OPM also appreciates that consumers are best protected by an external review process that ensures full development of each case prior to a final decision. OPM adopts the two fastest timeframes under current State law – 30 calendar days for the entire process, and 15 calendar days for the IRO’s decision – but will allow cases to be developed over a longer period of time, as necessary to ensure that sufficient information has been gathered and analyzed for each external review. The 15 days within which an IRO must decide a case will be counted within the 30 days for the overall process. We will evaluate whether this decision timetable best serves the interests of MSP enrollees.

13. Expedited External Review

The Tri-Department regulations (45 C.F.R. § 147.136(c)(2)(xiii)) require State processes to provide expedited external review for a denied claim that “concerns an admission, availability of care, continued stay, or health care service for which the [enrollee] received emergency services, but has not been discharged from a facility; or involves a medical condition for which the

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8 Standard external review is external review that is not expedited. Expedited external review is addressed under Standard 13.
standard external review time frame would seriously jeopardize the life or health of the [enrollee] or jeopardize the [enrollee’s] ability to regain maximum function.”

Similarly, the Interim Guidance requires that expedited external review be available under the HHS-administered Federal process upon receipt of notice of an initial adverse benefit determination if the determination “involves a medical condition of the [enrollee] for which the timeframe for completion of an expedited internal appeal . . . would seriously jeopardize the life or health of the [enrollee] or would jeopardize the [enrollee’s] ability to regain maximum function,” or if the determination “concerns an admission, availability of care, continued stay, or health care item or service for which the [enrollee] received services, but has not been discharged from a facility . . . .”

The Interim Guidance also requires expedited review to be available upon notice of a final adverse benefit determination (i.e., upon the issuer’s completion of the applicable internal appeal process and continued denial of services), “if the [enrollee] has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the [enrollee] or would jeopardize the [enrollee’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 [enrollee] received services, but has not been discharged from a facility.”

Note that the availability of expedited external review does not depend on the exhaustion of the internal appeal (or expedited internal appeal) process, subject to the exceptions discussed under Standard 3.

The Tri-Department regulations call for State processes to require that expedited external reviews be resolved as quickly as possible, and always within 72 hours. The HHS-administered Federal process also follows a timeframe of no more than 72 hours. Most State laws require a decision within 72 hours, and a few have shorter timeframes.

OPM recognizes the importance to consumers of a prompt decision, especially in cases where expedited review is warranted. On the other hand, each external review will undergo significant case development, which will depend on the receipt of information from the enrollee or authorized representative, issuer, and providers involved in the denied claim. In some States, the issuers, providers, and consumer assistance resources are accustomed to complying with shorter timeframes for expedited external review. Those in States with a 72-hour expedited timeframe, however, may not be. For example, a hospital in a State with a 24-hour timeframe likely has procedures for rapid resolution of an expedited request for external review on behalf of a patient during non-business hours. These procedures are likely to include provisions for seeking authorization to submit a request for expedited external review, submitting a request with a verification of the enrollee’s need for expedited review, and submitting supporting information, whereas a hospital in a State with a 72-hour timeframe may not have such procedures.

The standard for expedited external review under the MSP Program External Review Process will require the review to be resolved as quickly as possible, and within no more than 72 hours. In addition, OPM has concluded that the particularly compressed nature of expedited external
review and the impact of local norms on the resolution of expedited review warrant exceptions for MSP enrollees in some States. For enrollees in States with timeframes of less than 72 hours, OPM will require that expedited external review is completed within the timeframe otherwise applicable in the State.

14. Plan documents reflect right to external review

The Tri-Department regulations (45 C.F.R. § 147.136(c)(2)(xiv)) refer to Section 17 of the NAIC Model Act, which sets forth disclosure requirements regarding external review procedures for plans and issuers. Specifically, the NAIC Model Act requires issuers to “include a description of the external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage it provides” to covered persons. That description must include the enrollee’s right to seek external review, as well as a statement that the enrollee may be required to release certain medical records in connection with a request for external review.

States’ form review processes generally require plan documents describing MSP coverage to be reviewed and approved by State regulators. In addition, OPM reviews and approves such documents through the MSP Program application process. OPM will specifically review language in plan documents that describes the external review process to ensure that MSP enrollees are adequately informed of the right to seek external review.

15. Reporting and maintenance of records

Section 147.136(c)(2)(xv) of the Tri-Department regulations cite the record-keeping requirements of Section 15 of the NAIC Model Act, which addresses reporting to State regulators. The Interim Guidance calls for maintenance of records for 6 years, with records being available upon request to the relevant enrollee and issuer. OPM will require each contracted IRO to retain records for at least 6 years, to make such records available to enrollees and issuers, and to submit reports in a manner substantially similar to Section 15 of the NAIC Model Act.

16. Experimental or investigational treatment

The Tri-Department regulations (45 C.F.R. § 147.136(c)(2)(xvi)) require State external review processes to include procedures “substantially similar to what is set forth in Section 10 of the NAIC Model Act.” Section 10 is expansive and detailed. In general, State laws include denials involving experimental or investigational treatments within the scope of external review. A denial based on a finding that treatment is experimental or investigational falls within the scope of review under the MSP Program External Review Process.
If you have questions about the information provided in this letter, please contact Ellen Heier at Ellen.Heier@opm.gov.

Sincerely,

John O’Brien
Director of Healthcare and Insurance
Standards for the Multi-State Plan Program  
External Review Process (the Process):

1. Scope. Any denied claim is subject to the Process. Any rescission of coverage is also subject to the Process, regardless of whether the rescission is associated with one or more specific claim denials.
2. Notice. Multi-State Plan (MSP) issuers must provide adequate notice to enrollees of the right to seek external review from OPM. Such notice must include: (1) a statement of the enrollee’s right, (2) a statement that the enrollee may submit additional information (which will be shared with the issuer), and (3) a Privacy Act statement. Notice must be provided in plain language, and must be available in non-English languages pursuant to laws applicable in each State.
3. Exhaustion. Subject to three exceptions, an MSP enrollee must seek and be denied (in whole or in part) on internal appeal prior to requesting external review. Exhaustion of internal appeal processes is not required if: (1) the issuer waives the exhaustion requirement, (2) the issuer fails to comply with the requirements of its internal appeals process, unless such failure is de minimis, or (3) the enrollee simultaneously requests an expedited internal appeal and an expedited external review.
4. Filing fee. The Process will not have a filing fee.
5. Minimum dollar amount. Any denied claim is subject to the Process, regardless of dollar amount.
6. Time to file. Any MSP enrollee may request external review within one year of receiving a notice of adverse benefit determination or notice of final internal adverse benefit determination. Enrollees may request external review after the expiration of one year by providing a reasonable explanation for failing to request external review within one year. Enrollees in States without a time limitation for filing a request for external review will always be considered to have provided a reasonable explanation.
7. Assignment of IROs. OPM will assign an IRO to resolve any question involving medical judgment.
8. IROs. OPM will contract with one or more approved, accredited IROs.
9. Conflicts of interest. OPM will ensure that neither the IRO nor the individual reviewer within an IRO has a conflict of interest with the enrollee, issuer, or other relevant party.
10. Additional information. Enrollees will be permitted to submit additional information after submitting a request for external review. OPM will notify enrollees that any information submitted to OPM within 20 calendar days of OPM’s acceptance of a request for external review is guaranteed to be considered.
11. Binding decision. OPM’s or an IRO’s final decision on external review is binding on the issuer and the enrollee.
12. Time for decision. OPM will notify the issuer and the enrollee of a decision on external review no later than 30 calendar days after receiving a request for external review. For external reviews involving medical judgment, an IRO will have 15 calendar days to render a decision after receiving the request from OPM. The IRO’s 15 days will be counted as part of OPM’s 30 days. We will allow cases to be developed over a longer period of time, as necessary to ensure that sufficient information has been gathered and analyzed for each external review.
13. Expedited external review. OPM will resolve any valid request for expedited external review within 72 hours after receiving it. For enrollees in States with expedited external review timelines of less than 72 hours, OPM will comply with the timeline imposed under State law.
14. Notice in plan documents. The official statement of benefits for each MSP option will include an explanation of the Process and the enrollee’s right to external review.
15. Maintenance of written records. OPM will require that contracted IROs retain written external review records for no less than six years and make such records available to enrollees or issuers upon request. OPM will also retain written records for no less than 6 years and make such records available to enrollees or issuers upon request.
16. Experimental or investigational treatment. A denial based on a finding that a requested treatment is experimental or investigational is within the scope of the Process.