

**America's Health
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December 7, 2010

Office of Consumer Information and Insurance Oversight
U.S. Department of Health and Human Services
Attention: OCIIO-9986-NC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information – Federal External Review Process
(75 Fed. Reg. 70160, November 17, 2010)

Submitted Electronically via Federal eRulemaking Portal: www.regulations.gov

Dear Sir or Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments in response to the Request for Information (RFI) on procedures for the external review of benefit denials by health insurance plans. AHIP and its member health insurance plans have long supported a fair and timely process for consumers to appeal benefit denials through external review programs administered by independent third-party review organizations. We are committed to the successful implementation of the external review provisions of the Patient Protection and Affordable Care Act (ACA).

AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. AHIP's member health insurance plans offer a broad range of health insurance products in the commercial marketplace and also have demonstrated a strong commitment to participation in public programs.

The RFI solicits public input regarding standards for contracts between the Departments of Health and Human Services and Labor and Independent Review Organizations (IROs) to provide external review for self-funded group health plans and health insurance issuers in states that do not have an existing review process.¹ As discussed below, we believe that external review procedures should address three key issues to ensure a fair and transparent process: (1) consistent standards for IROs; (2) appropriate documentation of IRO decisions; and (3) sufficient timeframes for transitioning to the new procedures.

¹ A few states do not impose external review for benefit denials by health insurers. In a few other states, the external review process applies to some, but not all, types of carriers (e.g., Florida has an external review process for health maintenance organizations).

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Establishing Consistent Review Standards

Most IROs are accredited by URAC, pursuant to standards developed by that organization. URAC recently updated its standards to bring them into conformity with the ACA and the NAIC Uniform Health Carrier External Review Model Act (NAIC model act). These standards address a broad range of policies and procedures that IROs must implement, including requirements for the qualifications of medical reviewers, safeguards for the confidentiality of health information, conflict of interest standards, and provisions for the tracking and reporting of quality reviews.²

We believe the URAC accreditation process establishes consistent and appropriate operational standards for IROs. Independent external review organizations should maintain accreditation from URAC or comply with similar standards.

Documenting IRO Decisions

IROs are required by state laws and accreditation standards to provide the individual and the health insurance plan with the reasons for the IRO's decision to uphold or deny an adverse benefit decision. The NAIC model act also reflects this requirement. It is important that all parties are fully informed of the rationale for the decision, including a reference to any medical criteria or protocols. For this reason, if the IRO's determination is based on medical necessity, appropriateness, health care setting, level of care or effectiveness of a covered benefit, the decision should refer to the evidence-based medical or clinical guideline, protocol or other similar criterion that supports the decision. Providing the supporting rule or protocols will ensure a transparent process and help consumers and health insurance plans understand why the IRO reached its determination to uphold or overturn the appeal.

We recommend that any standards applied to IROs require that any decision based on medical necessity or other medical or clinical standards reference the guideline, protocol or other similar criterion that supports the decision.

Providing Time to Implement External Review Requirements

The Interim Final Rules and technical guidance issued by the agencies have established the following expectations with respect to the provision of external review:

- Health insurance issuers in states that have existing external review requirements (regardless of whether they apply to all insurers) are deemed to be in compliance with the

² In addition, most states have adopted specific requirements for IROs that provide external review for health insurers.

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ACA provisions until July 1, 2011. The Department of Health and Human Services (HHS) will review the state requirements to determine if they meet the minimum consumer protection standards of the NAIC model act.

- Health insurance issuers in states that do not have external review procedures must submit external reviews to the federal Office of Personnel Management (OPM).
- Self-funded group health plans must contract with at least three IROs to handle external reviews.

Health insurers and group health plans are working diligently to establish external review processes, however, there are several challenges:

- It is unclear which states will be determined by HHS to meet the minimum consumer protection standards of the NAIC model act. Assuming a state's law is found to not be in compliance, the state will need to establish new external review processes through legislation or regulation before July 1, 2011, and health insurers will need to implement the new provisions by that date.
- It is uncertain whether states without an external review process (either for all insurers or for a portion of the market) will establish such standards in time for health insurers to implement the procedures by July 1, 2011. In addition, the states cannot adopt enabling legislation or regulations until such time HHS issues guidance on the sections of the NAIC model act that constitute "minimum" consumer protections.
- It is not clear how the federal external review process for self-funded group health plans and for insurers in states that do not have fully compliant external review procedures will operate after July 1, 2011. Will the OPM review process continue? Will the agencies contract with IROs to provide external review, and will this process be voluntary, (i.e., can a self-funded group plan choose to contract with three IROs instead of using the designated agency IRO(s))?
- As we have noted in our previous comments on this issue, there continue to be concerns about the ability of self-funded group health plans to contract with at least three IROs in time to meet the July 1, 2011 deadline given the number of accredited review organizations. Currently, only thirty-six IROs have full accreditation from URAC and an additional nine IROs are in the process of accreditation or reaccreditation.³

³ This information was accessed on the URAC website on December 2, 2010 at: <http://www.urac.org/directory/DirectorySearch.aspx>

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- The expansion of the scope of review for the federal process – to include all coverage decisions in addition to denials related to medical necessity – will place further strain on the IROs and their ability to quickly respond to requests for external reviews.

As discussed, we fully support a full and fair process for review of benefit denials by an independent external review entity. It is critical that health insurance issuers and group health plans be given sufficient time to put these procedures into operation and that the agencies provide clear guidance and appropriate implementation timeframes.

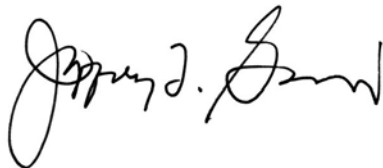
We suggest that the agencies provide guidance, as soon as possible, on the minimum consumer protection standards for the external review process so that all stakeholders, including consumers, health insurers, employers, and states, understand the procedures that will need to be implemented, either through state enabling legislation and regulation or by contract between the insurer or group health plan and the IRO. In addition, the agencies should clarify how the federal review process will function, including the future role of OPM and whether the agencies plan to contract with one or more IROs to provide external reviews.

If the agencies contract with IROs, then we further recommend that self-funded group health plans and health insurers have the option of either: 1) using the IROs under contract with the agencies, or 2) entering into contracts directly with available IROs, so long as federal standards are met. Finally, we urge the agencies to give health insurers and group health plans sufficient time to implement the new requirements – at a minimum, until plan or policy years beginning on or after January 1, 2012.

AHIP supports fair and timely external review processes and recommends the agencies provide guidance on the standards for state and federal external review procedures. Once this process is established, health insurance issuers and group health plans must be given sufficient time to implement any changes.

We appreciate the opportunity to work with the agencies on this important issue. If you have any questions, please feel free to contact my office.

Sincerely,



Jeffrey L. Gabardi
Senior Vice President