

[Billing Codes: 4150-65-P; 4510-29-P]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**45 CFR Part 147**

**Docket No. OCIO-9986-NC**

**DEPARTMENT OF LABOR**

**Employee Benefits Security Administration**

**29 CFR Part 2590**

**Affordable Care Act; Federal External Review Process; Request for Information**

**AGENCIES:** Office of Consumer Information and Insurance Oversight, Department of Health and Human Services; Employee Benefits Security Administration, Department of Labor.

**ACTION:** Notice; request for information

**SUMMARY:** This notice is a request for information (RFI) to gain market analysis information in advance of one or more future Requests for Proposals (RFP). On July 23, 2010, the Departments of Health and Human Services, Labor, and the Treasury published interim final regulations regarding, among other things, procedures for external review of health plan denials. The regulations include a provision for a Federal external review process in instances where there is no applicable State process. This RFI solicits information that will enable the Departments of Health and Human Services (HHS) and Labor (DOL) to conduct a market analysis and assist the Departments in planning and developing the Federal external review process. HHS and/or DOL may contract for services required to fulfill the statutory and regulatory requirements of the Federal external review process established under section 2719 of

the Public Health Service Act, as amended by the Affordable Care Act, and its implementing regulations.

**DATES:** Submit written or electronic comments by **[OFR: insert date 21 days from date of publication in the Federal Register]**.

We note that responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. The purpose of this RFI is to inform the RFP, not to gather public comments on the interim final rules for internal claims and appeals and external review processes under the Affordable Care Act; those comments are being collected and evaluated on a separate track. Information obtained as a result of this RFI may be used by the government for program planning and development on a non-attribution basis. Do not include any information that might be considered proprietary or confidential.

**ADDRESSES:** In commenting, please refer to file code OCIO-9986-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the instructions under the "More Search Options" tab.
2. By regular mail. You may mail written comments to the following address **ONLY**:  
Office of Consumer Information and Insurance Oversight,  
Department of Health and Human Services,  
Attention: OCIO-9986-NC,

Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW,  
Washington, DC 20201

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

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

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to

leave their comments in the OCIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the address indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:** Linda G. Greenberg, Department of Health and Human Services, Office of Consumer Information and Insurance Oversight at (301) 492-4225 or Amy Turner, Department of Labor, Employee Benefits Security Administration at (202) 693-8335.

**SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on the following public Web site as soon as possible after they have been received at: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at Room 445-G, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 1-800-743-3951.

## **I. Background**

Section 1001 of the Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111-148, added a new section 2719 to the Public Health Service Act (the PHS Act). The Affordable Care Act also added a new section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) incorporating the provisions of part A of title XXVII of the PHS Act (including PHS Act section 2719) into ERISA and the Code and making them applicable to group health plans and health insurance coverage in connection with group health plans. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) published interim final regulations implementing the provisions of PHS Act section 2719 on July 23, 2010, at 75 FR 43330.

Section 2719(b)(1) of the PHS Act and the Departments' regulations provide that, if a State external review process that applies to and is binding on a health insurance issuer 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"), then the issuer is not required to comply with the Federal external review process. State law may provide similar protection for group health plans that are not subject to ERISA preemption, such as nonfederal governmental plans. The Departments, through guidance, are authorized to establish an external review process that is similar to a State external review process that meets the standards set forth in the interim final regulations for group health plans and health insurance coverage if a State has not established such a process.<sup>1</sup>

## **II. Questions**

---

<sup>1</sup> The Departments' interim final regulations provide for a transition period for States until July 1, 2011 during which time HHS will work with States to assist them in making any necessary changes so that the State process provides, at a minimum, the consumer protections under the NAIC Uniform Model Act.

This RFI requests comments on operational issues associated with implementation of a Federal external review process for health coverage in States that do not have an applicable external review process that meets the minimum Federal standards. HHS and DOL plan to ensure consistent and uniform processes for external review by independent review organizations (IROs) within relevant geographic areas and throughout the nation. The Department of HHS and/or Labor may enter into one or more contractual relationships to implement the external review process and reserve the right to award one contract or several contracts depending on the workload and decisions on how to divide the workload of the Federal external review process, as necessary.

In particular, HHS and/or DOL may contract for services required to fulfill the statutory and regulatory requirements of the Federal external review process established under section 2719 of the PHS Act and its implementing regulations. In such a case, the contractor would be responsible for conducting standard and expedited reviews of all adverse benefit determinations and final internal adverse benefit determinations that are eligible for external review as defined by the regulations. Reviews would be conducted in an accurate, efficient, timely, and consistent manner. In conjunction with completing these reviews, the contractor may be tasked with the following functions and responsibilities to support the permanent Federal external appeals process:

- Development, maintenance, distribution, and update of “decision support” protocols;
- Adjudication of external review cases, using established protocols;
- Timely and accurate disposition of all external review cases;

- Collection, consolidation, storage, maintenance, and transmission of information regarding the receipt and disposition of external review cases for the Federal external review process;
- Performance of statistical and data analyses of external review cases to include trend analyses, and compliance with HHS data and reporting requirements including ad-hoc analyses for reports and inquiries from HHS, Congress, and other entities, and for purposes of continuous quality improvement;
- Participation and coordination with other entities (including other IROs) involved in the Federal external review process for quality improvement purposes;
- Communication of external review decisions to claimants and other parties involved in the case;
- Case management and documentation, which may include document imaging to produce a complete electronic case file; and
- Training all critical and qualified staff on all aspects of the external review process.

Accordingly, the Departments of HHS and Labor are seeking to engage formally, in a transparent and participatory manner, with the public on best practices and standards currently used by IROs. Specific questions are set forth below. Comments are invited from all stakeholders on these issues.

#### Qualified Organizations and Staff

(1) What accreditation standards currently apply to IROs?

- (2) What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?
- (3) What procedures are currently used by IROs to assure that reviewers do not have conflicts of interest with disputing parties?
- (4) What are IROs' current capacity for performing reviews? Does staffing and the time necessary for performing a review differ based on the type of claim (e.g., medical necessity, experimental/investigational treatment, coverage issues, etc.)?

#### Infrastructure

- (5) Please describe the type of data collection systems that IROs currently use to conduct analyses, reporting, and tracking of appeals and grievances.
- (6) Are the current data systems available in a secure, 508-compliant, web-based interactive structure?
- (7) What telecommunication systems and consumer technical support systems do IROs currently maintain for consumers (e.g., websites, 24-hour hotlines, helpdesk, and/or translation services for non-English speakers)?
- (8) What is a reasonable amount of time for a contractor to become fully operational (have all systems in place to conduct external reviews) after the date of a contract award? What resources would be necessary?
- (9) What considerations must be taken into account to smoothly transition from the current Federal interim external review process to a possible new permanent Federal external review process?

- (10) Do IROs currently operate nationally or in limited geographic areas? Would IROs that currently serve local areas be able to expand their service areas to possibly include other geographic areas such as other States? Are there any State and/or local licensing requirements?
- (11) Are there any special considerations HHS and/or DOL should be aware of in considering a specialized contract for urgent care appeals or for experimental and investigational treatments? Would such an approach have an impact on coordination?
- (12) Please describe the difference in standard operating procedures and resources (time, cost, personnel) for appeals that involve only medical necessity and those that involve both medical necessity and coverage questions.

#### Data Collection

- (13) What data are currently collected by IROs for tracking appeals and conducting analyses?
- (14) What steps are taken to ensure confidentiality and security protections of patient information?

#### Evaluation

- (15) Do IROs (or subcontractors) currently conduct evaluations of their operations? Do such evaluations include an assessment of how easy it is for consumers to access and use the external review process in a timely manner? Do evaluations result in quality improvement initiatives? If so, what are some examples of quality improvement initiatives undertaken by IROs?
- (16) What specific requirements should be applied to IROs to evaluate progress toward performance goals? What performance goals are the most appropriate?

OCIIO-9986-NC

Signed at Washington, DC November 10, 2010.

---

**Elizabeth Fowler,**  
Director of Policy,  
Office of Consumer Information and Insurance Oversight.  
Department of Health and Human Services.

OCIIO-9986-NC

Signed at Washington, DC November 9, 2010.

---

**Phyllis C. Borzi,**  
Assistant Secretary,  
Employee Benefits Security Administration  
Department of Labor.

[FR Doc. 2010-28876 Filed 11/12/2010 at 11:15 am; Publication Date: 11/17/2010]