NAIRO
National Association of Independent Review Organizations

December 8, 2010

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, S.W.
Washington, DC 20201

Attention: Docket No. OCIIO-9986-NC *(delivered electronically)*:

The National Association of Independent Review Organizations (NAIRO) is pleased to respond to the Request for Information (RFI) in connection with the Federal External Review Process under the Patient Protection and Affordable Care Act (PPACA) and related technical releases. NAIRO, with 20 members, represents the majority of URAC-accredited independent review organizations (IRO). NAIRO's mission is to protect the integrity of the independent medical review process.

To facilitate your review, we have replicated the specific questions posed in the RFI and have provided our corresponding responses. Should you have any questions or concerns regarding our response you can reach Gib Smith directly at 571-436-2670 or gibpsmith@gmail.com.

Kind regards,

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NAIRO Members:

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Alicare Medical Management, Salem, NH
AllMed, Inc., Portland, OR
Considine & Associates, Laguna Hills, CA
HQSI, East Brunswick, NJ
IMEDECS, Lansdale, PA
IPRO, Inc., Lake Success, NY
Lumetra, San Francisco, CA
MCMC LLC, Bethesda, MD
MRIoA, Inc., Salt Lake City, UT
MPRO, Farmington Hills, MI
MMRO, Novi, MI
NMR, Inc., Trevose, PA
NMRRA, Albuquerque
Permedion, Westerville, OH
PMSCO, Harrisburg, PA
Prest & Associates, Inc., Madison, WI
ProPeer Resources, Inc., Bountiful, UT
The P&S Network, Beverly Hills, CA
SFUR, Coral Gables, FL

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Introduction

Response to Request for Information, file code OCIIO-9986-NC

Recently, The Department of Health and Human Services and the Department of Labor published 29 CFR Part 2590, Affordable Care Act; Federal External Review Process; Request for Information (RFI). This document is presented by the National Association of Independent Review Organizations in reply to that RFI.

NAIRO is responding to provide a broad overview of the independent review organization (IRO) industry from the perspective of our URAC-accredited IRO member organizations. Many IROs intend to submit their own comments to this RFI. NAIRO's response is designed to foster a better understanding of the IRO industry as a whole. NAIRO, representing 20 accredited IROs, respectfully requests an opportunity to meet with OCIIO to provide further information and answer additional questions as part of this RFI process.

About NAIRO

The National Association of Independent Review Organizations (NAIRO) was formed in 2001 by a group of URAC-accredited IROs. With more than 20 URAC-accredited members, NAIRO is the undisputed expert in independent review.

The need for uniform regulations from state to state and a uniform application process is what brought NAIRO together. One of the primary objectives of NAIRO is to simplify the regulated independent review organization application process and independent medical peer review requirements among the states.

NAIRO is dedicated to protecting the integrity of the independent medical peer review processes. Utilizing the expertise of hundreds of board-certified clinicians throughout the country, NAIRO members embrace an evidence-based approach to independent medical peer review, in order to resolve coverage disputes between enrollees and their health plans.

Responses to RFI Questions

1. What accreditation standards currently apply to IROs?

URAC is currently the only accrediting body that has specific IRO standards. Accredited IRO's comply with a set of Core standards which apply to every type of URAC healthcare accreditation (utilization management, health plan, etc.) and an additional set of 17 specific Independent Review (IR) standards. The Core standards include the following topics:

Organizational Structure
Policies and Procedures
Regulatory Compliance
Inter-Departmental Coordination
Oversight of Delegated Functions
Marketing and Sales Communications
Business Relationships
Information Management
Quality Management
Staff Qualifications
Staff Management
Clinical Staff Credentialing/Oversight Role
Health Care System Coordination
Consumer Protection and Empowerment

The IR standards include the following:

Organizational Structure
IR-1 Initial Case Review
IR-2 Conflict of Interest Process
IR-3 Reviewer Conflict of Interest Assessment
IR-4 Reviewer Credentialing
IR-5 File Documentation
IR-6 IRO Log
IR-7 Telephone Access
Independent Review Process
IR-8 Reviewer Qualifications
IR-9 Reviewer Case Selection
IR-10 Medical Necessity/Appropriateness
IR-11 Experimental/Investigational Case Processing
IR-12 Administrative/Legal Case Processing
IR-13 Additional Information Processing
IR-14 Multiple Reviewer Cases
IR-15 Decision Notice
IR-16 Decision Time Frames
IR-17 Expedited Review Process

2. What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?

Credentialing in required by all IROs and URAC-accredited IROs adhere, at a minimum, to the following standard:

IR - 4 - Reviewer Credentialing:
The organization establishes and implements selection criteria for reviewers, and implements a program to verify current unrestricted credentials (prior to assignment of any reviews), and re-verify at least every three years, the qualifications of all reviewers. At a minimum, such a program shall address:
(a) Verification of professional credentials, including:
(i) Current licensure;
(ii) Current board certification, if applicable;
(iii) History of sanctions and/or disciplinary actions; and
(iv) Professional experience;
(b) Potential conflicts of interest.

Because the nature of IRO work is such that some number of cases proceed on to legal proceedings, most IROs go far beyond the

basic requirements of URAC standard IR-4 and do much more comprehensive credentialing which may include primary source verification of education, residency, fellowships, admitting privileges, criminal background checks, searches of the National Practitioner Data Bank, professional society actions, and malpractice proceedings.

Legal reviewers undergo the same rigorous credentialing process except their credentials and lack of sanctions are verified through their respective state associations or legal licensing agencies. It should be noted that neither the Uniform Model Act nor the Interim Final Rules define minimum qualifications for a legal expert reviewer.

3. What procedures are currently used by IROs to assure that reviewers do not have conflicts of interest with disputing parties?

URAC-accredited IROs adhere to standards IR-1, IR-2 and IR-3 which define a process for identifying both organizational conflicts as well as reviewer conflicts. URAC defines conflict of interest as:

Any relationship or affiliation on the part of the organization or a reviewer that could compromise the independence or objectivity of the independent review process. Conflict of interest includes, but is not limited to:

- *An ownership interest of greater than 5 percent between any affected parties;*
- *A material professional or business relationship;*
- *A direct or indirect financial incentive for a particular determination;*
- *Incentives to promote the use of a certain product or service;*
- *A known familial relationship;*
- *Any prior involvement in the specific case under review.*

The definition is further honed in IR-3 which relates specifically to reviewers who are required to verify on each case that they do not:

(a) Have a material professional, familial, or financial conflict of interest regarding any of the following:

(i) The referring entity;
(ii) The health benefits plan;
(iii) The consumer;
(iv) The attending provider or any other health care provider previously involved in the case;
(v) The facility at which the recommended treatment would be provided; or
(vi) The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the consumer;

(b) Accept compensation for independent review activities that is dependent in any way on the specific outcome of the case; or
(c) Have involvement with the case prior to its referral to independent review.

IRO's additionally align their conflict of interest requirements with the NAIC's Model Act and the Patient Protection and Affordable Care Act definitions.

From an independent review workflow perspective, NAIRO IROs continually check for COIs throughout the workflow process. This includes COI checks upon review receipt, prior to and during reviewer case assignment and prior to case closing.

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.)?

There are forty-four (44) URAC accredited IROs. NAIRO is comprised of 20 of these accredited IROs. In order to conduct internal appeals and/or external reviews IROs establish large panels of medical experts. These panels are each comprised of hundreds if not thousands of medical specialists and other experts on a national basis with extensive clinical and legal experience. This volume of experts further offers a wide range of specialties and subspecialties available for review selection. The number of experts available through the NAIRO IROs alone exceeds 10,000.

Current statistics indicate approximately 1.3/10,000 participants exercise their right to external review, thus, the volume of reviews on a national basis is relatively low. The annual total volume of new external appeals from non-grandfathered plan is estimated to be 2,800 in 2011 and by 2013 only increase to 6,900. Given the depth and capacity the IROs have with the panels they have established, even significant increases in these statistics would not present any issues. NAIRO member organizations are simply not at capacity with regard to the volume of work they can perform. Additionally, IRO's have the capability to continually recruit experts. This provides them with the ability to easily expand their panel to meet demands on an as needed basis.

Therefore, NAIRO is confident that the current number of accredited IRO's is more than sufficient to adequately handle the volume of reviews anticipated as a result of the regulations stemming from the Interim Final Rules and related Technical Releases.

Staffing and the time for performing reviews does vary based not only on the types of reviews as indicated above, but also on the size of the reviews, the number of questions being addressed in each review, requirements for peer-to-peer telephone conferences and attempts, panel reviews, notice requirements, and application of criteria/medical policies/rules. There is great variation in the length of time and staff resource associated with each type of review, and these variations are largely defined on a customer-by-customer basis as each customer operates in a different state with different rules governing their internal and external appeal processes.

5. Please describe the type of data collection systems that IROs currently use to conduct analyses, reporting, and tracking of appeals and grievances.

There is great variation among IROs in terms of the types of data collection systems they use, but every IRO has some means of tracking and reporting on basic elements which include at a minimum the following:

- The date the organization received the request to conduct an independent review from the referring entity;
- The date upon which the organization received the initial information packet from the referring entity;
- The date by which the organization must receive additional information from the referring entity, consumer, or attending provider.

- The date any additional information was received.
- A description of the issue to be resolved;
- The name of the referring entity;
- Whether the case was expedited or not;
- The organization's determination regarding the case;
- The date the organization's determination was issued; and
- The date the organization's determination was sent to the appropriate parties.

This minimum set of data elements allows for very basic reporting of findings, turn around times, and types of reviews by client, state, etc. This minimum reporting, however, does not generally meet the needs of IRO customers (health plans, TPA's, etc.) who want much more granular reporting on items such as level of review (pre-authorization, appeal, external appeal, etc.), specialty/procedure requested, peer-to-peer call attempts, etc. As a result of these customer requirements, all IROs track many more data elements than the minimum set, but each IRO has a varied set of data they collect to meet their customer's needs.

6. Are the current data systems available in a secure, 508-compliant, web-based interactive structure?

This question will need to be answered individually by IROs, but as an association we do know that the responses to this question will be varied depending on the size of the IRO and the types of customers they service. All accredited IROs have data-systems whether electronic or paper-based which are secure and confidential.
Most external review work does not involve ongoing interaction with consumers so many organizations may not have systems directly geared at consumers. Assuming the process stands which allows the covered person/authorized representative to submit additional written information, this process and interaction with the covered person typically occurs through hard copy correspondence.

Some IROs use web interfaces to track and transmit cases, and some IROs have no web interface. To a large degree, the manner in which cases are transmitted to and from the IRO and clients will depend on the client's technology rather than the IRO's technology. Many clients still work with paper records and transmit them via fax or mail. Other clients have electronic records and they can transmit cases and receive responses electronically. IRO's are in the business of accommodating this wide range of client needs. In terms of the data storage and tracking systems, the actual system in use and the security around that system will be different at each IRO.

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)?

Again, each IRO will need to answer this question in regard to their own capabilities, but all URAC-accredited IROs are required to maintain 24-hour systems to receive and respond to requests. Most IRO work does not involve direct contact with consumers (unless the IRO is acting as a delegated entity to support UM functions) so many organizations may not have systems directly

geared at consumers. For those IROs that provide direct interface with consumers on behalf of their clients, there are URAC standards to ensure consumer rights and responsibilities are communicated, consumer satisfaction is assessed, and health literacy needs are met. Every URAC-accredited IRO is required to identify consumer safety issues and maintain an on-going method for reporting safety concerns to clients.

We understand the requirement that notices must be provided in a culturally and linguistically appropriate manner. If an IRO does not have in-house staff available to translate, translation services are available to facilitate written and verbal communications.

IROs provide external review services for multiple clients with each client having different requirements due to number of plan participants, meeting various population thresholds and various non-English languages. As previously discussed, the rate of use for external reviews is low. It is unlikely that all requirements could be fulfilled for every client for all potential languages without supplemental support from a translation service

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?

Each IRO will have differing implementation time requirements, though most IROs are already geared to doing this work and have already designed their systems to conduct external reviews as they are in the process contracting with health plans and TPAs who need to meet the requirements of PPACA. As an organization, NAIRO expects our IROs could be fully operational in a very short timeframe, if not upon contract award.

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?

The changes in processes that will have the greatest effect on transitioning from one process to a new permanent process will be those that affect timing, notice requirements, and reporting requirements. Changes in reporting and notice requirements will generally require IT support with an IRO to re-program existing systems. Timing changes affect internal processes and can also have an affect on peer specialty reviewers and their ability to handle volumes of cases. The most important things to consider when writing new regulations for a permanent process will be clear guidelines around data collection and reporting, clear guidelines about timing requirements for both the health plan functions and the IRO functions, and clear guidelines about notice content requirements.

NAIRO IROs have the proven independent workflows and staff and reviewer resources to make this transition seamless.

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 possible include other geographic areas such as other States? Are there any State and/or local licensing requirements?

This will vary amongst IROs. However, most of the NAIRO IROs provide national independent review coverage. The question of expansion is a business decision that each IRO will have to make individually.

A few states have same-state licensure requirements for physicians making determinations on cases and to respond to these requirements IROs generally contract with physicians across the United States to meet their same-state licensure requirements. NAIRO recommends that same state licensure requirements be eliminated. This will help ensure that the eligible health care consumers in each state receive state of the art reviews based on the most up-to-date standards of care.

Each state has differing rules around these requirements and to which type of reviews these rules apply also varies from state to state. Clear guidance as to this point in the permanent Federal rules as they apply to external appeals would be greatly appreciated.

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?

All IROs currently review urgent care appeals and experimental and investigational treatments (E/I). A specialized contract is not necessary. The 72-hour expedited timeframe allowed in PPACA and the NAIC Model Act is not onerous to IROs. IROs are accustomed to handling urgent requests when clinically necessary. In terms of E/I treatments, all IRO determinations are based on evidence-based findings and peer specialty reviewers are skilled at making these determinations. Some IROs and their clients may choose use a panel approach to E/I reviews and make the final determination based on consensus, but this is largely defined by client needs and not by IRO choice.

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.

IRO panels are comprised of medical and legal specialists. IROs will provide a specialty- matched physician review for a medical necessity appeal whereas a legal expert would be used for an issue involving coverage questions. When a case involves both medical necessity and a coverage question, an IRO will use both a clinician and a legal expert.

Any variations in standard operating procedures and resources would be addressed in the responses from each individual IRO.

13. What data are currently collected by IROs for tracking appeals and conducting analyses?

This issue was answered in question 5 above: There is great variation among IROs in terms of the types of data collection systems they use, but every IRO has some means of tracking and reporting on basic elements which include at a minimum the following:

- The date the organization received the request to conduct an independent review from the referring entity;
- The date upon which the organization received the initial information packet from the referring entity;
- The date by which the organization must receive additional information from the referring entity, consumer, or attending provider.
- The date any additional information was received.
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- Whether the case was expedited or not;
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This minimum set of data elements allows for very basic reporting of findings, turn around times, and types of reviews by client, state, etc. This minimum reporting, however, does not generally meet the needs of IRO customers (health plans, TPA's, etc.) who want much more granular reporting on items such as level of review (pre-authorization, appeal, external appeal, etc.), specialty/procedure requested, peer-to-peer call attempts, etc. As a result of these customer requirements, all IROs track many more data elements than the minimum set, but each IRO has a varied set of data they collect to meet their customer's needs.

14. What steps are taken to ensure confidentiality and security protections of patient information?

IROs are considered Business Associates under HIPAA regulations. As such IRO contracts incorporate BA agreements that apply HIPAA privacy and security standards to IROs just as they are applied to covered entities under the law. Each IRO has differing internal procedures for ensuring confidentiality and security, just as each client has differing requirements within their contracts. For the most part, IROs have very high security standards and some undergo specialized security audits or hold URAC accreditation in healthcare security. IRO employees as well as peer reviewers are all trained in HIPAA privacy and URAC also maintains a set of standards in their Core standards to ensure compliance with confidentiality requirements.

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?

All NAIRO member IROs have quality improvement programs in place, as required by URAC accreditation.

As mentioned above, most IRO business comes from plans and TPAs and not directly from consumers, but URAC also requires IROs to track any grievances related to access to services and to develop quality improvement projects around any issues related to access. Each IRO does its own evaluations and those will vary from company to company, but accredited IROs will all have a formal quality improvement program available for review. Some quality improvement initiatives undertaken by IROs include topics around consumer safety, turn-around-time improvement, accuracy of review products, peer reviewer consistency, and customer service improvements.

16. What specific requirements should be applied to IROs to evaluate progress toward performance goals? What performance goals are the most appropriate?

Performance goals need to be based on criteria that are easily measurable and reportable. The criteria should be objective and not subjective so it lends to quality measurement and improvement.

In regard to external appeals, performance goals could be based on turn-around times and consumer access to services.