


NAIRO



National
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Organizations

White Paper:
**How to Interpret the New Internal
and External Appeals Regulations**

Introduction..... 3
 How to Interpret the New Internal and External Appeals Regulations 3
 About NAIRO 3
 Overview..... 3
 Applicability 3
 How Does the Act Affect Your Plan’s Practice?..... 4
 Internal Claims and Appeals..... 4
 External Review Process 5
 Federal External Review Process 6
 Self-Funded Plans 6
 Issuers 7
 Failure to Comply 8
 Common Questions or Issues Encountered Under PPACA and IFR: 8
 Interpreting the 3 IRO rule under DOL Technical Release 2010-01, Section A.3 8
 Conflict of Interest under PPACA and the related Technical Release 8
 IROs and Fiduciary Capacity..... 10
 Conclusions..... 12
 Sources..... 14

Introduction

How to Interpret the New Internal and External Appeals Regulations

Understanding the new internal and external appeal provisions of Section 2719 of the Patient Protection and Affordable Care Act (PPACA) and the related Department of Labor (DOL)/Department of Health and Human Services (HHS) technical releases (collectively the Interim Final Rules or IFR) is no simple task. NAIRO has created this document to help appeal stakeholders to better understand these new rules under the IFR and how it affects their business and relationships with independent review organizations (IRO). The sections below provide an overview of some of the critical issues and concerns related to the IFR.

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 to achieve uniform regulations from state to state is what brought NAIRO together. Among the primary objectives of NAIRO are 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 physician specialists 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.

Overview

The IFR published jointly by DOL, HHS, and the Department of Treasury earlier this year provide the standards for processing internal claims and appeals; the basis for determining when plans and issuers must comply with applicable state external review processes or federal external review processes; and the minimum requirements that state external review processes must meet. The more recently published DOL Technical Releases 2010-01 and 2010-02 and HHS address the federal external review processes, providing interim procedures for self-insured health plans and model notices for both internal claims and appeals and for external review processes.

Applicability

PPACA requires all non-grandfathered health plans to comply with standards for both internal claims and appeals and external review processes. These requirements apply only to non-grandfathered health plans as of the first plan year beginning after September 23, 2010 (January 1, 2011, for calendar year plans). However, about half of employer plans will lose grandfathered status on the first day of their coming plan years.

How Does the Act Affect a Plan's Practice?

Internal Claims and Appeals

Group health plans and issuers offering group or individual coverage are required to implement an effective internal claims and appeals process. As a starting point, group health plans must adopt the DOL's regulations governing internal claims and appeals procedures in accordance with Section 503 of the Employee Retirement Income Security Act (ERISA). Plans and issuers must also modify their claims procedures to meet a number of additional requirements:

- **Expanded definition of adverse benefits determination.**
Adverse determinations that are subject to these new claims and appeals processes include a denial, reduction or termination of, or a failure to provide or make a payment for a benefit. The regulations also expand upon this definition by including any rescission of coverage, regardless of whether any particular benefits have been denied.
- **Reduced timeframe for deciding urgent care claims.**
The regulations reduce the timeframe for deciding urgent care claims and notifying claimants from no later than 72 hours to no later than 24 hours after receipt of the claim by the plan.
- **Additional protections to ensure a full and fair review.**
The plan must provide the claimant, at no cost, any new evidence that is considered, relied upon, or generated by the plan in connection with the claim. Before a final internal adverse decision is rendered, the claimant must be provided, free of charge, with the rationale for the decision so that the individual has an opportunity to respond prior to that date.
- **Avoiding conflicts of interest.**
The regulations require that all claims and appeals must be decided in a manner that ensures the independence and impartiality of the person making the benefits determination. Decisions regarding the hiring, compensation, termination, promotion, or similar matters of a claims adjudicator or medical expert cannot be based upon the likelihood that the individual will deny a claim. (For more detail, see the "Conflicts of Interest" section below.)
- **Culturally and linguistically appropriate notices.**
Notices to enrollees regarding benefit determinations must be provided in a culturally and linguistically appropriate manner. Notices must be provided in a non-English language if the number of participants who are literate only in the same non-English language exceeds certain thresholds, which are adapted from the DOL's regulations regarding style and format for summary plan descriptions. Oral notices involving urgent care can be provided in English as long as the follow-up written notice is provided in the appropriate non-English language.
- **Additional content requirements for notices.**
Notices of adverse benefit determinations must contain the date of service, healthcare provider, claim amount, diagnosis code, treatment code, and the meanings of the codes. The reasons for the adverse decision must also include the denial code and an

explanation of the code. The notice must also include a discussion of any plan standard used in the determination, a discussion of the claim and appeal procedures, and the contact information for any applicable consumer assistance office.

- **Strict adherence to the claims procedures.**

Failure to “strictly comply” with all the requirements results in the claimant being deemed to have exhausted the claims and appeals procedures, which allows the individual to initiate an external review and pursue other applicable remedies (e.g., bringing legal action). “Substantially complying” with the rules or *de minimus* errors still trigger the deemed exhaustion of the internal procedures. This rule substantially raises the stakes for plans and, to the extent applicable, sponsors should make certain that their third-party administrators (TPAs) are complying with the new rules and determine whether their TPAs are or should be contractually liable for any related failures.

- **Continued coverage during an appeal.**

Claimants must be provided continued coverage while waiting for an internal appeal decision. Plans and issuers must comply with requirements of the DOL claims procedures regulations, which generally prohibit a plan or issuer from reducing or terminating an ongoing course of treatment without providing advance notice and an opportunity for advance review. In addition, individuals in urgent care situations and individuals receiving an ongoing course of treatment may be allowed to proceed with an expedited external review at the same time as the internal appeals

process, under either a state external review process or the Federal External Review Process.

External Review Process

In addition to the internal claims and appeals procedures, non-grandfathered plans and issuers of non-grandfathered policies must adopt either a state external review process or the Federal External Review Process. Most health insurance issuers, insured plans, certain self-funded plans, and multiple employer welfare plan arrangements will generally be subject to state external review processes in states that have processes in place. However, HHS will determine whether a state external review process meets minimum standards, which were set forth by the consumer protections in the Uniform Health Carrier External Review Model Act of the National Association of Insurance Commissioners (NAIC Model Act).

Alabama, Mississippi, Nebraska, and North Dakota are the only states that did not have external review processes when the Act was enacted. Plans that are not subject to their state’s processes, plans in the states with no processes, and those in states that do not meet the minimum standards of the NAIC Model Act after July 1, 2011, must comply with the Federal External Review Process, which requires plans to contract with at least three URAC-accredited IROs to conduct the external review in order to ensure unbiased and independent decisions. The DOL Technical Release 2010-01 (section A.3) also explains that under the Federal External Process all ERISA or self-funded plans must contract with three URAC accredited IROs to ensure independence and eliminate bias.

Plans in states with external processes that do not apply directly to them (some state processes only apply to HMOs, for example) may choose to voluntarily participate in the state's process rather than the federal process if the state will expand their coverage to these plan types.

Technically, the Federal External Process applies only to those states without an already established external review process in place. The ERISA self-funded plans really have two choices: (1) to follow their respective state external review laws or (2) to follow the federal process. However, many self-funded plans do not want to submit to the External Review regulations, but many states have indicated that they will not allow these plans to follow their external review laws, making it hard to predict the impact of this ruling on IROs. Although, while not required, many plans seem to be opting for the Federal external review route which requires three IROs under 2010-01.

A transition period will allow states an opportunity to amend their laws to meet the NAIC external review standards. If a state has not amended its laws to satisfy the minimum requirements by July 1, 2011, issuers and plans that were once subject to the state's insurance laws will have to comply with the federal process.

Federal External Review Process

The regulations provide that self-funded ERISA plans and plans and issuers in states without a state external review process that meets minimum standards of the NAIC Model Act must comply with the Federal External Review Process. Those plans in states with no external review process at all must comply with HHS interim federal process for which they have issued technical

guidance available at:

http://www.hhs.gov/ociio/regulations/consumerappeals/interim_appeals_guidance.pdf

The Federal External Review Process will generally apply to all adverse benefit determinations, but adverse benefit determinations related to eligibility are not within the scope of the federal external review.

The agencies recently issued a joint notice setting forth interim safe harbor standards for complying with the Federal External Review Process for self-insured group health plans and for issuers. The safe harbor provides plans an extension until July 1, 2011, with respect to some of the standards in the interim regulations, including the standard regarding substantial compliance with the regulations. This safe harbor is described in the DOL Technical Release 2010-02, released September 20, 2010, and is available at:

<http://www.dol.gov/ebsa/newsroom/tr10-02.html>.

Self-Funded Plans

For plan years beginning on or after September 23, 2010, and until future guidance is issued, self-funded plans will be considered to be in compliance with federal external review requirements if they either: comply with the federal external review procedures set forth in Technical Release 2010-01; or voluntarily comply with a state's external review process, if the state expands access to its external review process to plans that are not subject to state law. The agencies intend to issue future guidance no later than July 1, 2011, to replace the interim Federal External Review Process.

Issuers

For plan years (and policy years in the individual market) beginning on or after September 23, 2010, and until future guidance is issued, issuers in states without a state external review process that meets minimum standards of the NAIC Model Act will be deemed to be in compliance with federal external review requirements if they comply with an interim compliance method to be determined by HHS. HHS will issue guidance as to which state external review laws satisfy the minimum standards of the NAIC Model Act. The agencies intend to issue future guidance no later than July 1, 2011, to replace the interim Federal External Review Process.

For standard external reviews, self-funded group health plans must comply with the following requirements:

- Allow a claimant to file a request for an external review for up to four months after the date of receipt of a notice of an adverse benefit determination.
- Within five business days of receipt of the external review request, the plan must complete a preliminary review of the request to determine whether:
 - The claimant was covered under the plan at the time the item or service was requested or provided;
 - The adverse benefit determination does not relate to the claimant's failure to meet eligibility requirements;
 - The claimant has exhausted the plan's internal appeals process unless the claimant is not required to exhaust the internal appeals process under the regulations; and
 - The claimant has provided all necessary information and forms to process an external review.

- Within one business day after completing the preliminary review, the plan must issue a written notification to the claimant. If the request is complete but not eligible for external review, the notice must include the reasons why the request is ineligible and contact information for the Employee Benefits Security Administration. If the request is incomplete, the notice must describe the information needed to make the request complete and claimants must be allowed to perfect the request within the four month filing period or within 48 hours of receipt of the notice, whichever is later.
- Assign an accredited IRO to conduct the external review. To ensure unbiased and independent decisions, plans must contract with at least three IROs and either rotate claims among them or use other independent, unbiased methods for selection, such as random selection. Contracts between the IRO and the plan must satisfy certain requirements.
- The IRO must review the claim *de novo* and is not bound by any decisions or conclusions reached during the plan's internal claims and appeals process.
- If the IRO reverses the plan's adverse benefit determination, the plan must immediately provide coverage or payment for the claim.

Self-funded health plans must also allow for expedited external reviews under certain circumstances. The process for an expedited external review mirrors the process for a standard external review except that the plan must immediately determine if a request is eligible for external review and must provide all necessary documents and information to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

Failure to Comply

If a plan or issuer fails to “strictly adhere” to the internal claims procedure requirements, a claimant is deemed to have exhausted the internal claims and appeals procedures and may initiate an external review and pursue any available remedies under applicable law. Courts will review any such claims without giving deference to the plan or issuer.

In addition, group health plans that fail to comply with the requirements may be liable for excise taxes equal to \$100 for each day of noncompliance with respect to each individual to whom such failure relates.

Common Questions or Issues Encountered Under PPACA and the IFR:

Interpreting the 3 IRO rule under DOL Technical Release 2010-01, Section A.3

Issue: Are plans required to contract with three IROs 2010-01?

The requirement to implement a new Federal External Review Process applies only to plans in those states without existing external review regulations. These states include Alabama, Mississippi, Nebraska and North Dakota. For these states, each eligible plan is required to contract with three URAC-accredited independent review organizations (IRO) to ensure independence and eliminate bias. Please note the “3 IRO rule” does not apply to internal appeal processes that require no change for plan providers.

However, there are some mitigating circumstances where the “3 IRO Rule” may apply to plans in other situations. Pursuant to this release, states may choose to expand access to their external review laws to those plans that are not subject to these laws, such as self-insured plans. These plans can voluntarily choose to comply with these state external review laws. It also appears under this section that plans can voluntarily comply with these states’ external review laws that would otherwise not be applicable or available.

As outlined earlier, it is NAIRO’s understanding, pursuant to a recent meeting with DOL, that many of the self-insured plans are choosing not to comply with state external reviews, instead opting to be subject to the Federal External Review Process. Additionally, several states have indicated that they will not expand their external review requirements to include self-insured plans, which would make them subject to the proposed Federal External Review Process. In both situations, these plans would be required to comply with the three IRO Rule.

Conflict of Interest under PPACA and the related Technical Release

Issue: Do IROs have a conflict of interest under PPACA and the related Technical Releases if they perform internal and external reviews for the same client?

NAIRO does not believe that an accredited IRO that performs both internal and external claims for the same client has any conflicts of interest related to this practice. Below we provide our rationale that supports this position.

Accredited IROs have long been subject to stringent COI standards. These standards as defined by URAC, NAIC, and many state regulatory bodies have been strictly followed by URAC accredited IROs. Pursuant to these rules each IRO must furnish a certification that the it has evaluated its professional independence and objectivity with respect to the review being performed and has concluded that it is independent and objective.

DOL regulations have required that, in order to provide the claimant with a reasonable opportunity for a full and fair review, group health plans must provide claims procedures in which the reviewer is “neither an individual who was consulted in connection with the adverse benefit determination that is the subject of the appeal, nor the subordinate of any such individual.” [Source: 29 CFR § 2560.503-1(3)(ii)]

According to the IFR and PPACA Section 2719, IROs do not have a COI unless they offer decision incentives, such as compensation and employment as outlined under Section 2719 - *Eliminating Conflicts Of Interest*, which are precluded under URAC Standards and many state laws. PPACA – Section 2719, deals with decision-related incentives. Accredited IROs meet the stringent COI standards outlined in the NAIC Model Act.

Finally, URAC accredited IROs are also subject to URAC’s stringent COI standards spelled out in the definitions of URAC IRO Standards 4.0 and the proposed IRO Standards 5.0 standards, which are listed below:

URAC 4.0 Standards – Conflict of Interest: 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.***

URAC 5.0 Standards – COI: Under the proposed URAC IRO 5.0 Standards, in particular *IR 8 - Reviewer Conflict of Interest Attestation*, reviewers must attest that they do not have a COI for each case accepted. The attestation includes the following:

- *The reviewer does not accept compensation for review activities that is dependent in any way on the specific outcome of the case;*
- ***To the best of the reviewer’s knowledge, the reviewer was not involved with the specific episode of care prior to referral of the case for review; and***
- *The reviewer does not have a material professional, familial, or financial conflict of interest regarding any of the following:*
 - *The referring entity;*
 - *The insurance issuer or group health plan that is the subject of the review;*
 - *The covered person whose treatment is the subject of the review and the covered person’s authorized representative, if applicable;*
 - *Any officer, director or management employee of the insurance issuer that is the subject of the review;*

- Any group health plan administrator, plan fiduciary, or plan employee;
- The health care provider, the health care provider's medical group or independent practice association recommending the health care service or treatment that is the subject of the review;
- The facility at which the recommended health care service or treatment would be provided; or
- The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the covered person whose treatment is the subject of the review.

However, there are a few exceptions in the state-mandated external review market. For example, North Carolina, Pennsylvania and a few other states have stringent regulations about IROs working with private clients not reviewing any state cases under consideration for those clients. This is the exception rather than the norm.

From NAIRO's perspective, an IRO should avoid using any reviewer who had any involvement in a specific review at a different level of the review process. We also suggest IROs let clients know that they check reviewer conflict of interest throughout the review process including case assignment, reviewer assignment, and prior to case closing. Further, the proposed IRO Standards to be released in July 2011 indicate that the IRO must disclose who their internal clients are to potential external review clients to avoid conflict of interest.

Based on the foregoing, IROs do not have a conflict of interest under PPACA, the IFR and the technical releases.

IROs and Fiduciary Capacity

Issue: NAIRO has heard many comments regarding whether or not IROs should serve in an ERISA Fiduciary role.

NAIRO strongly advocates against IROs serving as fiduciaries for the following reasons:

- If an IRO or the reviewers acting on their behalf are deemed ERISA fiduciaries they must comply with ERISA Rule 404. This rule requires that a fiduciary must discharge their duties with respect to a plan solely in the plan interest of the participants and beneficiaries and:
 - for the exclusive purpose of: (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan;
 - with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims;
 - by diversifying the investments of the plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so;
 - in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this title and title I;

[Source: ERISA Section 404(a); 29 U.S.C. §1104(a)]

If the ERISA fiduciary fails to meet or breaches these fiduciary standards, they are liable to plan participants,

beneficiaries and other plan fiduciaries.
 Such liability includes:

- ♦ *Restore any losses to a plan;*
- ♦ *Restore any profits gained;*
- ♦ *Equitable Relief, including removal of fiduciary and all other available relief;*
- ♦ *20 percent civil penalty;*
- ♦ *Prohibited Transaction Excise Tax;*
- ♦ *Criminal penalties if intentional violation.*

By serving in a fiduciary capacity, the IRO incurs the obligations and exposure that directly results in increased costs and related risks. It is NAIRO's belief that many IROs will decline this role or simply choose not to perform these types of reviews. As detailed below, this increased liability and exposure is inconsistent with the NAIC Model Act URAC IRO Standards, the IFR, PPACA and the spirit of health care reform itself.

Serving in a fiduciary capacity eliminates the perception and reality of IRO independence. In this capacity, not only are we working directly for the employer/plan, we are now standing in their stead. As such, we are liable for the results of the plan's decision. Not only is this a perceived conflict, it is huge disincentive to be independent when faced with the threat of potential lawsuits and fines. Further, acting as a fiduciary is in direct contravention to Section 14 of the NAIC Model Act, which mandates that the IRO and its reviewers are to be held harmless for their recommendations.

*Serving as a fiduciary is also in direct contravention to the IFR conflict of interest (COI) rules, URAC COI standards and NAIC COI standards. For example, under the proposed COI rules outlined in PPACA – Section 2719 – **Eliminating Conflicts Of***

***Interest** these interim final regulations require plans and issuers to ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision.*

***Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood or perceived likelihood that the individual will support or tend to support the denial of benefits.** [Source: IFR]*

It can easily be perceived that by serving as a fiduciary that IROs and their reviewers would support the plan administrator's decision, particularly in light of the increased risk of exposure to liability.

If an IRO is deemed a fiduciary then for all intents and purposes they are required to follow the terms of the plan. This in direct contravention to Technical Release 2010-01 that mandates an IRO will consider the terms of the plan only "to the extent the information or documents are available and the IRO considers them appropriate" and then as only one of several factors the IRO takes into account when rendering its decision

URAC accredited IROs are also subject to URAC's stringent COI standards spelled out in the URAC IRO Standards 4.0 and the proposed 5.0 version (to be implemented in January 2011), both of which are listed above. In fact under 5.0, IROs are specifically excluded from serving as a fiduciary. Under these standards serving as a fiduciary can easily be perceived as a direct financial incentive for a specific determination, particularly when the IRO wants to avoid the possibility of legal

liability. This is something that is strictly prohibited by URAC and state external review laws.

The NAIC Model Act has COI provisions similar to URAC's IRO standards. Under the Act, like the URAC IRO Standards, acting as a fiduciary creates the opportunity for the perception of direct and indirect financial incentives as it relates to supporting plan decisions.

Current reimbursement for external review services do not account for the IRO accepting any fiduciary risk. As indicated above, serving as a fiduciary to self-insured plans or in any capacity is a huge disincentive for IROs to perform independent review services because of the potential liability incurred. Many IROs are smaller organizations especially in comparison to the plans providing the coverage and do not possess the financial and legal resources to offset the inevitable related legal costs whether or not the issue is actually litigated. Many IROs would refrain from providing services in this market in order to avoid the potential liability associated with serving as a fiduciary.

Please note that many liability carriers have indicated to NAIRO members that they will not cover the IRO if they choose to serve in a fiduciary capacity where financial restoration is required as part of the fiduciary arrangement with the plan.

NAIRO recommends that IROs provide standards-based determinations which the plan administrator or plan fiduciary either accepts as binding or gives significant weight. It remains the plan's choice as to how to best use the IRO's recommendation. Another option is to create an established presumption in favor of the IRO recommendation for these entities.

Under these scenarios, the plan or their fiduciary retains the final decision-making authority. The IRO recommendation only becomes binding when and if the plan administrator or the fiduciary chooses to accept it as its final decision. This helps to ensure that the plan administrator or their fiduciary receives a conflict free, unbiased review and the IRO is able to eliminate the possibility of incurring fiduciary liability. This position is supported by the ERISA Industry Committee and the Claims Appeal Fiduciary Services, Inc.

Conclusions

These new internal claims and appeals procedures and external review procedures apply only to non-grandfathered group health plans and individual policy issuers. Employers who are considering design changes to their existing plans that would result in the loss of grandfathered status should consider the administrative issues and costs involved with complying with these new procedures.

In the case of insured plans, the issuer has primary responsibility to comply with the regulations and the latest guidance. Plan sponsors should consider confirming that the issuer will comply with the new internal claims procedures and external review requirements.

In the case of self-funded plans, plan sponsors who are involved with claims administration, including those who outsource claims administration to a TPA but retain authority to decide final internal appeals, will have to comply with the new requirements.

Keep in mind that most health insurance issuers, fully-insured plans, certain self-funded plans, and multiple employer welfare plan arrangements will generally be subject to existing internal appeals process, and many will carry on under existing state external review process.

HHS' new Federal External Review Process applies only to those plans in the handful of states without existing regulations. Other plans in states with external review programs that do not apply to them are required to contract with at least three URAC-accredited IROs to conduct the

external review. Payers and their IROs need to discuss processes to put in place to avoid conflict of interest. Specifically, keeping the specialist for these external reviews separate from the one for internal reviews, because the Federal External Review Process requirements do not affect other types of reviews.

Finally, IROs should not serve as fiduciaries because of the apparent conflicts of interest this role creates. An IRO serving as a fiduciary is in direct contravention to Section 2719, which is designed to ensure IRO independence and objectivity.

Sources

This document was adapted from an original white paper entitled: “Healthcare Reform: How to Interpret the New Internal & External Appeals Regulations” produced in November 2010 by AllMed Healthcare Management, Inc., a NAIRO member.

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