



National Association of Independent Review Organizations

Dedicated to protecting the integrity of
the independent medical review process

Understanding the Vital Role of Independent Medical Review and Utilization Review Services

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I. Introduction

Purpose of This Paper

Recent legislation has brought independent medical and utilization review — a well-established pillar of health care delivery residing at the juncture where payers and consumers meet — to the forefront of the health care industry.

The purpose of this white paper is twofold. First, we seek to identify a number of timely issues at the center of recent legislation and court decision making related to the provision of independent medical and utilization review services.

Second, the paper seeks to give voice to the National Association of Independent Review Organization's (NAIRO) identification of relevant issues from the perspective of all stakeholders — including independent review organizations (IROs), health plans and consumers. NAIRO is comprised of many of the thought leaders in this industry.

In so doing, NAIRO will foster a greater understanding of the often-complex independent medical review process. NAIRO also will develop a roadmap aimed to dispel negative perceptions of independent medical review functions and, accordingly, will issue a series of strategies aimed to help IROs avoid and overcome barriers standing in the way of fully maximizing the contributions to better health care made by the independent medical and utilization review process.

Mission of NAIRO

NAIRO is comprised of the majority of URAC-accredited IROs. NAIRO has more than 30 members and is dedicated to protecting the integrity of the independent medical and utilization review processes. Utilizing the expertise of thousands of board-certified clinicians at a national level, NAIRO members embrace an evidence-based approach to independent medical peer review in a continuous effort to help resolve coverage disputes between enrollees and their health plans.

A Brief History of IROs

For decades, health insurance regulators have helped resolve disputes between patients and their health plans. With the rise of managed care in the latter half of the 20th century, an increasing number of patient appeals have revolved around the language of a patient's health plan to deny or limit coverage. Most often, denials or limitations of coverage pertain to judgments about medical necessity or appropriateness of care.

Not long after managed care came to the fore, many states began to pass legislation requiring independent review (originally called external review) of adverse health care benefit decisions made by

commercial health plans.¹ The Patient Protection and Affordable Care Act (PPACA, also commonly referred to as ACA) of 2010 added to the laws, policies and scope of independent review. Together, these distinct mandates, arriving from state and federal levels, seek to ensure that the final decisions about an individual's care are made on the basis of sound medical judgment rather than being driven by financial or business considerations.

In 1978, Michigan became the first state to establish an independent review program. Medicare established an independent review program in 1985. Since that time, state-mandated independent review has grown considerably, and today the vast majority of states plus the District of Columbia mandate and regulate independent external review.

Other forces contributed to the rise and spread of independent review as well. In 2000, the National Committee on Quality Assurance (NCQA), an organization that accredits health plans, expanded its accreditation standards to require that plans make the independent review process available when a health plan issues a medical necessity denial.

In 2002, a Supreme Court decision opened the door to more extensive state regulation of health maintenance organizations (HMOs). The 2002 case *Rush Prudential HMO vs. Moran* posed to the court the following question: Did Rush Prudential, a fully insured ERISA (Employee Retirement Income Security Act) health benefit plan, have to comply with state law and submit to independent review? More specifically, was Rush Prudential required by law to act in accordance with the Illinois HMO Act, a separate piece of legislation that required binding independent review when an HMO disagrees with the decision of a patient's physician that a treatment is medically necessary? The answer, in short, was yes. The Court ruled that the Illinois HMO Act was not preempted by ERISA, and this signal decision led to the presumption that the majority of state laws requiring independent review of benefit denials can be enforced against HMOs.

In 2010, PPACA significantly elevated the concept of independent reviews of adverse benefit decisions. PPACA made clear that state laws relating to internal and external independent review, as it applies to fully insured health plans, will not be pre-empted by ERISA. Further, PPACA requires all states to either substantially conform their independent review laws to the National Association of Insurance Commissioners' (NAIC) Uniform Health Carrier External Review Model Act or elect to use a federally mandated process. In either case, states are required to adhere to strict, standardized rules for independent review.

PPACA also stipulated that all self-insured group health plans and health insurance issuers are required to contract with three IROs to review appeals for members who have exhausted all internal appeal levels available to them. While health plans are allowed to conduct first- and second-level appeals internally, many health plans have turned to IROs to perform these internal reviews as well. Ultimately, PPACA has been a driver of uniformity and transparency in the review and appeals process.

¹ Independent medical review processes trace back to 1978, when Michigan became the first state to enact an IRO law. Kaiser Report, March 2000, Revised. By March 2000, 33 states had enacted IRO laws. May 2002.

II. Brief Overview of Review Process

Defining Internal and External Appeal Options

In the course of receiving medical treatment, a health care consumer may encounter a denied claim, which occurs when a particular service (a test or treatment, for example) is considered to not be covered by the consumer's health plan. When a consumer's claim is denied, he or she has the option to file an appeal. In general, there are three steps in an appeals process:

- 1) A first level internal appeal.
- 2) A second level internal appeal. (There may be one or two levels of internal appeal, depending on the plan type and design.)
- 3) A third level external appeal.

The third level appeal is the only step that must occur on an external basis, meaning it is completed by an organization other than the health plan — which is where the term *external review* comes from.

External review often occurs after a health plan's internal appeals process has been exhausted, although many leading health plans retain IROs at the internal appeal level as well. The role of the IRO during the external review process is to act as an objective arbiter and determine, based on plan language, evidence-based medicine and regulatory requirements, whether the services in question meet the criteria for coverage under the health insurance plan.

While the review decisions are not binding at the internal-review level, external appeals are by nature binding decisions.²

Recently, the health care industry has witnessed an increase in the number of administrative external appeals, which don't require medical judgment, but instead demand legal review of policies, procedures and applicable law to ensure a health plan is properly applying legal provisions to health care denials. As a result, the need for an IRO is greater than ever because the IRO ensures an independent review of payer practices and decisions in a health care landscape that is rapidly changing.

Independent reviewers include board certified or licensed physicians, physician advisors, allied clinicians and other health care professionals and legal specialists.

Depending on whether a consumer is insured under a fully insured or self-funded health care plan, different laws regulate the appeal process. For fully insured plans, individual states regulate external appeals. Each state may have its own process or may use the federal-run process. Most states use their own state-run process. For self-funded plans, ERISA under the Department of Labor (DOL) regulates external appeals. (*See the chart, below, for some of the main differences between self-insured and fully insured plans.*)

² Some states, e.g., Iowa, do allow for a court review of an external review decision by its own terms.

Differences Between Plans

Question	Fully Insured	Self-Funded
Who makes coverage decisions on the internal appeals process?	The health plan provider.	Third-party administrator (TPA) working on behalf of the employer offering the self-funded plan.
Who conducts internal appeals?	Often they are conducted by the clinical reviewers or staff employed by the health insurance provider or an IRO.	Clinical reviewers working for a third-party administrator or an IRO.
Who regulates external appeals?	These are regulated by a state insurance commissioner. There are currently four states without state-regulated reviews: Alabama, Mississippi, Nebraska and North Dakota. These states must follow federal external review requirements.	Regulated by ERISA under the U.S. Department of Labor.
Who conducts external appeals?	An IRO approved by the state insurance commission. (Unless the federal process supersedes, when either the federally contracted IRO is used or one of the three IROs contracted by the health plan.)	IROs contracted by the health plan and accredited by URAC or other nationally recognized accrediting organization.
What does it cost a patient to make an appeal?	There is no cost for internal appeals. Some states have a minimal charge that can be refunded if the external appeal is successful.	There is no cost for appeals.
Where can consumers go to find out about the appeals process?	Resources include the consumer's human resources department; plan document, customer service desk or website; or state insurance commission office or website.	Employee Benefits Security Administration (DOL-EBSA) website.

III. Current Challenges Facing Independent Review for Consumers and Payers

Independent medical review providers face ongoing challenges in their collective effort to provide fair and impartial medical review. Some challenges, such as an underutilization of medical review, affect the business side of the independent review process. Others, including a perceived conflict of interest and lack of awareness of reviewer qualifications, pertain instead to the quality of independent reviews.

The series of tables below depicts the primary challenges having an impact on the efficacy of medical review and the sustained business solvency of this important – and growing – piece of the health care arena.

Reversing Underutilized External Review Services

Challenge #1: Underutilization of External Review Process	Affects Payers	Affects Consumers
<ul style="list-style-type: none"> Lack of understanding of the role of IROs 	✓	✓
<ul style="list-style-type: none"> Lack of consumer knowledge of external appeal rights and process 		✓
<ul style="list-style-type: none"> Implementation challenges 	✓	✓
<ul style="list-style-type: none"> Lack of confidence in independent review 	✓	✓

While the scope and role of independent review has grown significantly over the past five years, few consumers utilize this process. For example, a recent study conducted by AHIP found that, on average, less than one out of every 10,000 eligible individuals requested an external review of their denied health claim.

Recent legislation, such as the ACA, has gone to great length to solidify the important role of external review within the health care system. Additionally, financial regulations in the insurance market – perhaps most visible in the medical loss ratio (MLR) provision of the ACA – are increasingly shifting review operations to IROs, which specialize in such services.

Yet challenges remain. Consumer knowledge of the right to external appeal lags. General understanding of the role and function of IROs is underwhelming. And consumer confidence is low. Yet the independent review process provides the consumer with an easily accessible “check and balance process” to ensure their claim is properly determined. As a result, further promotion of the IRO process is necessary to educate consumers regarding their vital rights. Furthermore, the independent review process can save time and expense for the consumer, the health plan and the health system overall.

Amid this challenging backdrop, NAIRO continues to work diligently to expand the knowledge base of consumers and to ensure its member organizations are in a position to lead the industry to a stronger future.

For consumers, NAIRO approves of the recent spate of consumer protections that emerged from the ACA and other laws. NAIRO encourages continued education among both consumers and health plans so that all stakeholders can take advantage of the benefits of independent review.

Additionally, NAIRO members offer expanded services to both health plans and consumers. As part of external and internal review, today’s URAC-accredited IROs are equipped to deliver three types of utilization review services:

- Retrospective reviews, conducted after services are provided to a patient.
- Concurrent reviews, which take place during a hospital stay or course of treatment.

- Prospective reviews, also known as pre-certification reviews or prior authorizations, which occur before a patient is admitted or receives treatment.

By adapting to the new needs of the market, the versatility of many leading IROs brings added strength to the independent review process, ensuring that health plans and consumers have a trusted partner when the need for independent review arises.

Accredited Versus Non-Accredited IROs

Challenge #2: Selecting an Appropriately Qualified IRO	Affects Payers	Affects Consumers
• Accredited vs. non-accredited IROs	✓	✓
• Adherence to rigorous standards of practice	✓	✓

It is important for the overall integrity, consistency and accuracy of the independent review process to use an accredited IRO. Accredited IROs adhere to specific, rigorous standards of practice, which promote a review process that is fair and transparent. Indeed, lawmakers placed such importance on the adherence to these standards of practice that the use of accredited IROs is mandated under the ACA.

Accredited review organizations undergo a thorough screening process and standardize their entire operations to provide review for consumers and payer organizations. By using only accredited IRO organizations, health plans and consumers gain assurance that appeals receive a comprehensive review and objective decision. A quick glance at accreditation standards shows that IROs:

- Are up to date on all federal and state regulations, organizational processes, data security and internal operations;
- Work with appropriately licensed and credentialed peer reviewers who are current on the latest medical standards and technologies.

Within the health care industry, accreditation is considered the gold standard for independent review organizations. Consumers can rely on accredited IROs to ensure consistency, efficiency and accuracy in internal and external review recommendations. More information on IRO accreditation standards is available at www.urac.org.

Overcoming Time Constraints

Challenge #3: Time Constraints Related to Case File Documentation	Affects Payers	Affects Consumers
• Lack of time to secure the patient’s medical records and other information leads to an inadequate review	✓	✓
• Acquiring additional documentation from the consumer		✓

The inability to secure complete case file documentation in a timely manner can adversely impact the integrity of the independent review process. From the time an IRO accepts an external review request, an insurance provider has five business days to supply the IRO with relevant case documents. The

patient is granted 10 days in some cases to disclose pertinent case information to the IRO; some states allow five business days. Given the concise timeframe, obtaining the necessary documentation and files in an exhaustive manner can prove challenging.

NAIRO continues to work with legislative bodies, industry leaders, health plans and other stakeholders to ensure IROs and their reviewers have sufficient time to collect the information necessary to make accurate and timely decisions.

Steps to Ensure a Quality Report and Decision Notes

Challenge #4: Ensuring a Quality Report	Affects Payers	Affects Consumers
<ul style="list-style-type: none"> Stakeholder concern that IRO reports are not complete 	✓	✓

Some of this challenge can be tied to obtaining sufficient case records. Documentation is the key to a quality report that fairly and accurately represents the issue under external review. Once sufficient documentation is received and evaluated, the rules and regulations related to creating the review report are quite comprehensive. For example, the NAIC Model Act requires an IRO to return a written decision on the adverse determination to the patient, the patient’s representative (if applicable), the health plan and the insurance commissioner within 45 days of the review submission for standard reviews, and within 72 hours for expedited reviews. Some states, such as Illinois, typically require the decision in much less time (20 days or less).

To reach an evidence-based decision, the IRO must consider certain elements of a case, including the following items (to the extent the information and documents are available), according to the NAIC Model Act:

- The covered person’s medical records;
- The attending health care professional’s recommendation;
- Consulting reports from appropriate health care professionals and other documents submitted by the health carrier, covered person, the covered person’s authorized representative or the covered person’s treating provider;
- The terms of coverage under the covered person’s health benefit plan with the health carrier to ensure that the IRO’s decision is not contrary to the terms of coverage under the covered person’s health benefit plan with the health carrier;
- The most appropriate practice guidelines, which shall include applicable evidence-based standards and may include any other practice guidelines developed by the federal government, national or professional medical societies, boards and associations;
- Any applicable clinical review criteria developed and used by the health carrier or its designee utilization review organization; and
- The opinion of the independent review organization’s clinical reviewer or reviewers after considering the case elements listed directly above.

When issuing a final notice, the IRO is required to include significant elements of the case, including:

- An overview or general description of the reason leading to the request for the external review;
- The date the IRO received the assignment to conduct the external review;
- The date the external review was conducted;
- The date of the IRO’s decision;
- The principal reason/s for the IRO’s decision, including which evidence-based standards were used to render the decision, if applicable;
- The rationale for its decision; and
- References to the evidence or documentation, including the evidence-based standards, considered in reaching its decision.

One challenge is that each state may vary its requirements slightly, since the Model Act is a minimum requirement. Thus, the lack of uniformity creates a potentially burdensome process. URAC accreditation standards (and the state laws that follow the Model Act, as required by the ACA) require IROs to provide the clinical reviewer’s qualifications in the determination notice as well as specific citations to supporting evidence or references that the reviewer used to make the determination.

Experimental And Investigational Reviews

Challenge #5: Performing Experimental and Investigational Reviews	Affects Payers	Affects Consumers
• Health plan’s terms of coverage vary	✓	✓
• State regulations and coverage vary	✓	✓
• Medical necessity vs. experimental treatment	✓	✓

Many therapies often involve complex and cutting-edge treatment options. When such advanced treatments are requested, disputes regarding the appropriateness and necessity can be commonplace between payers and plan participants.

Each case will require an in-depth review of plan provisions, evidence-based findings that demonstrate the effectiveness of the treatment under review and the unique case-specific issue and history of the member in question. Certain treatments may be considered appropriate in some cases and not indicated in others, depending on all factors under review.

If a health plan denies coverage for a given service or treatment as experimental/investigational, the patient has the right to appeal the denied claim. When this situation occurs, IROs step in to assess the claim and determine if the services in question meet the criteria for coverage under the health insurance plan.

When IROs consider appeals of experimental/investigational cases, they follow a legal framework that considers several factors. Specifically, IROs and their clinical reviewers assess two factors:

- **FDA approval.** Clinical reviewers assess whether the recommended service or treatment has been approved by the FDA for the patient’s condition.
- **Evidence-based standards and/or medical or scientific evidence.** Also, clinical reviewers will study the evidence to see if “the expected benefits of the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any

available standard health care services or treatment and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments,” according to the NAIC Model Act.

With the expertise of clinical reviewers and specialized knowledge of health care services, accredited IROs are equipped to make evidence-based decisions about these types of appeals.

More specifically, accredited IROs offer:

- **Deep expertise and experience.** IROs have immediate access to physicians and allied health care practitioners who are at the vanguard of medical treatments and services. Accredited IROs provide expertise in experimental and investigational reviews and are up-to-date on the accepted standards of care.
- **Large panels of clinical reviewers.** IROs feature expansive reviewer panels of hundreds to thousands of experts, who can provide access to all recognized specialties and sub-specialties.
- **Affiliations to leading research and knowledge centers.** Many IRO reviewers are affiliated with or have relationships with medical centers of excellence and research hospitals, which links them to the latest knowledge and resources of accepted medical practices and treatments.
- **Advanced, ongoing education and training.** The training and credentialing programs for IROs are designed to ensure the use of reviewers who are knowledgeable about the most current peer-reviewed literature and evidence-based medicine.

Reviewer Qualifications

Challenge #6: Adequate Reviewer Qualifications	Affects Payers	Affects Consumers
<ul style="list-style-type: none"> • When reviewers are not in the same or similar specialty as the issue under review or otherwise not qualified to perform the review 	✓	✓

URAC accreditation standards devote multiple sections to reviewer qualifications, underscoring the importance of having experts render often complex medical recommendations.

URAC standards require that a clinical reviewer holds confirmed expertise on the topic under review. The standards also require that IROs independently verify the reviewer’s stated qualifications to guarantee that the reviewer’s credentials and experience are up to date. At a minimum, accreditation standards require that independent reviewers:

- Hold a current, non-restricted licensure or certification for clinical practice in a state of the United States;
- Have at least five years of experience providing direct clinical care to patients;
- Are clinical peers (meaning the reviewer is in the same licensure category and same or similar specialty as the treating provider); and
- Have professional experience in the area of practice “that typically manages the medical condition, procedure, treatment, or issue under review” (URAC standards, IR 4).

Importantly, accreditation standards also require that clinical reviewers are knowledgeable on the trends of current practice, stating that reviewers of external review cases must have experience providing direct clinical care to patients within the past three years (URAC standards, IR. 6).

Further, the URAC standards require that IROs gain primary source verification of the reviewer’s licensure or certification and board certification, if applicable. IROs must also collect information regarding direct clinical care experience, including the date/s and length of the experience. The standards also require IROs to verify disciplinary action or sanctions against the medical professional. The NAIC Model Act stipulates that IROs may not use reviewers who have a history of sanctions or disciplinary action.

Conflict of Interest

Challenge #7: Minimizing Conflict of Interest	Affects Payers	Affects Consumers
<ul style="list-style-type: none"> Perceived conflict of interest 	✓	✓

Accredited IROs adhere to several standards and guidelines intended to avoid issues of conflict of interest, including guidance within the Model Act and URAC accreditation standards.

The Model Act states that IROs must act as separate business entities from health plans (Section 13, C). Specifically, the Act stipulates that IROs “may not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise control with a health benefit plan, a national, state or local trade association of health benefit plans, or a national, state or local trade association of health care providers.”

Further, URAC accreditation standards mandate certain requirements for review organizations that provide both internal and external review services. To be in compliance with URAC’s conflict-of-interest standards, if required by the state they are doing business in IROs must disclose the names of the organizations for which it provides internal review. This information must be provided even if the IRO has non-disclosure agreements with its internal review clients. For external reviews, “the referring entity [generally the state] has the opportunity to forward these cases to a different organization for external review if a conflict is determined” (URAC standards, IR 13(b)).

Reviewer Conflict of Interest

Of particular concern for conflict-of-interest issues is the role of the reviewer, who provides a decision on the claims appeal. Both the NAIC Model Act and URAC standards address reviewer conflict-of-interest requirements.

URAC standards stipulate that the reviewer:

- Will not receive compensation for the review decision dependent on the outcome of the case;

- Was not involved in the specific case in question; and
- Has neither professional, familial or financial ties with any involved parties (the consumer, health plan, treatment facility, etc.) that could be considered leading to a conflict (URAC standards, IR 8).

The standards also require accredited IROs to assign a different reviewer, who has had no previous involvement with the case, for each level of review. Each assigned reviewer must complete a rigorous internal conflict-of-interest check, based on the factors stated above, before accepting a case.

IV. NAIRO's Efforts to Achieve a Fair, Impartial Review Process

As a leader in delivering greater transparency and impartial appeals decisions to the independent medical review process, NAIRO is engaged in continuous efforts to streamline and improve the independent review process for its constituents and stakeholders, including health plans and consumers.

NAIRO is engaged with legislative leaders on a state level in jurisdictions throughout the country. NAIRO's legislative and regulatory committee, comprised of more than a dozen leaders in independent review, keeps tabs on state laws and pending legislation that will have an impact on the industry. The driving goal of the legislative and regulatory committee is to ensure that laws governing the independent medical review process adhere to quality standards that meet measures of excellence, and to monitor conflicting legislative language that could negatively impact the review process.

Additionally, NAIRO collaborates with federal agencies, such as the Department of Labor (DOL) and other industry leaders, such as NAIC, to ensure health care quality standards are met throughout the length of the medical review process. Leaders from NAIRO also are in active and ready contact with the accreditation bodies that issue the quality standards that govern much of the internal and external review processes. For example, NAIRO, as part of a stakeholder working group, recently collaborated with the Wyoming Department of Insurance to help the agency develop and implement the state's external review laws.

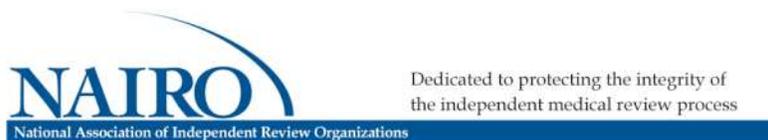
V. Summary

The future of independent medical review is bright. The recent and ongoing strengthening of the independent review process, experienced most directly through the ACA's mandates requiring greater uniformity among states, has served the industry well.

Yet challenges to a fully optimized system remain, and recognition among stakeholders about the significant and important role of IROs is something that the independent review industry continues to cultivate. As this paper details at length, NAIRO continues to identify the current issues and barriers that can prevent an effective and meaningful independent review process for all stakeholders.

Under the leadership of NAIRO, accredited IROs and other NAIRO member organizations are taking proactive steps to resolve and mitigate these issues and barriers. NAIRO and its members stand willing to collaborate with all stakeholders of the independent medical review process to ensure a fair, balanced and effective system for all parties involved.

For further information on the independent review process and organizations that provide these services, visit NAIRO online at www.nairo.org.



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