



PRESERVING THE INTEGRITY AND VIABILITY OF INDEPENDENT MEDICAL REVIEW

EXECUTIVE SUMMARY

Independent review continues to play an important role in American health care. Currently, forty four states and the District of Columbia mandate independent “external” review of disputed medical necessity and/or experimental/investigational treatment decisions by health plans. Independent review organizations (IRO’s) provide qualified experts to review cases in which there is a dispute between the patient and the health plan. Utilizing the expertise of hundreds of board certified clinicians throughout the country, NAIRO (National Association of Independent Review Organizations) member organizations embrace an evidence based approach to independent review. Among the substantiated benefits of independent review are: patient protection, cost effectiveness, positive impact on health plan review processes and other health care management activities, and reduction of costly litigation.

As the role of independent “external” review has grown, health plans have sought independent review to assist them with “internal” levels of decision. This is consistent with the industry and accreditation understanding of the factors that make a review *independent*, regardless of whether it is an “external” or “internal” review. An independent review is *free from financial or relational conflict of interest*. The requestor/purchaser *does not select the peer reviewer*. The independent review is *advisory and consultative*, that is, it is *not a determination of benefits*. There are fundamental and critical differences between *independent review* and *utilization management*. There are fundamental and critical differences between *independent review* and *utilization management* (formerly called “utilization review”). Unlike utilization management, independent review is *not* a coverage decision or a determination of benefits, and is *not* performed by a reviewer affiliated in any way with the health plan.

Despite the fundamental distinction between independent review and utilization management, IRO’s encounter a number of regulatory barriers and restrictions that seriously impede their ability to contribute to the independent “internal” review process. In addition, some states have imposed a number of complex, redundant, and in some cases counterproductive mandates on the performance of independent “external” review.

The members of NAIRO believe that an informed, evidence based review, free of bias and conflict of interest, is an invaluable asset to the health care system., and recommends the following recommendations to legislators, regulators, and health plans:

- 1. Accept URAC Independent Review Organization (IRO) Accreditation in Lieu of State Certification**
- 2. Provide Statutory Immunity for IRO's and Reviewers for Activities Conducted in Good Faith**
- 3. Base Independent Review on the Best Available Medical Evidence; Adopt a Medical Rather than Legal Decision Making Model**
- 4. Eliminate Same State Licensing Requirements for Reviewers**
- 5. Guarantee Anonymity for Reviewers**
- 6. Recognize that independent review is not utilization management. Therefore, IROs should not be required to seek licensure or the equivalent as utilization management entities.**
- 7. Accept IRO Credentialing of Reviewers in Lieu of Individual States' Requirements**
- 8. End the Exclusion of Single-Specialty IRO's**

INTRODUCTION

Definition

In its 2005 Medical Management Industry Profile, URAC defines Independent Review as “a process, independent of all affected parties, to determine whether a health care service is medically necessary, medically appropriate, and/or experimental/investigational. Independent Review typically (but not always) occurs after all appeal mechanisms available within the health benefits plan have been exhausted. Independent Review may be voluntary or mandated by law.”¹ It is a formal and unbiased process for the resolution of disputes involving adverse benefit determinations and is usually conducted by a medical expert or panel of medical experts who are not affiliated with the health plan. The expert medical reviewer(s) must be qualified to perform the review; he/she/they, by board certification, knowledge, and experience, are considered peers of the treating provider(s).

¹ URAC, an independent, nonprofit organization, is well known as a leader in promoting health care quality through its accreditation and certification programs. URAC accredits organizations based on the medical management practices in which they engage. (Medical management refers to a broad array of practices used to improve quality and reduce cost.) These practices include Utilization Management (UM), Case Management (CM), and Independent Review (IR) as well as the rapidly expanding fields of Disease Management (DM) and total population management services, such as call centers, that help participants with consumer directed health care decision making. This definition of independent review is cited from *URAC, Trends and Practices in Medical Management: 2005 Industry Profile*, 2005, hereinafter referred to as *URAC 2005 Medical Management Report*.

Independent Review Organizations and Accreditation

Typically, Independent Review Organizations (IRO's) have a small full time staff and maintain extensive panels of licensed, credentialed, board certified medical professionals who are experts in their area of review. IRO's contract with a variety of entities, including federal or state agencies, health plans, and third party administrators, to conduct independent reviews of disputed denials of health care benefits.

In October 1999, URAC announced its intention to accredit IRO's to encourage their voluntary use by private health plans. The formal URAC accreditation process began in 2000. For an IRO to receive URAC accreditation, it must meet URAC's stringent standards, which ensure that the IRO: is free from conflicts of interest, maintains established qualifications for medical reviewers, has the expertise to address medical necessity and experimental/investigational treatment issues, meets reasonable time frames for standard and expedited reviews, and maintains an appeal process.² At present, 33 IRO's have current full URAC accreditation.

The National Association of Independent Review Organizations (NAIRO) represents a substantial portion of URAC-accredited IRO's and requires that all of its member organizations maintain full URAC accreditation. NAIRO is dedicated to promoting the value and protecting the integrity of the independent medical review process. Utilizing the expertise of hundreds of board certified clinicians throughout the country, NAIRO member organizations embrace an evidence-based medical review approach to resolve coverage disputes between enrolled members and their health plan.

Historical Background

A long standing role of health insurance regulators has been to help resolve disputes between patients and their health plans. With the rise of managed care, an increasing number of these disputes involve health plan decisions to deny or limit coverage based on judgments about the medical necessity or appropriateness of care. One of the most important developments in the past decade is the adoption of state legislation requiring independent review of adverse health care benefit decisions by commercial health plans. Fueled in part by the backlash against managed care, these mandates (initially "external" review requirements) sought to ensure that the final decisions about an individual's care are made on the basis of sound medical judgment rather than financial or business considerations alone. In 1978, Michigan became the first state to establish an independent review program. Since then, Medicare established an independent review program (1985) and state mandated independent review has exploded. Currently, forty four states plus the District of Columbia mandate and regulate independent review.³ Effective July 2000, the National Committee on Quality Assurance

² URAC *Core Standards, Version 1.1* and *Independent Review Standards, Version 2.0*

³ Since February 2004, the only states which have not established regulation of independent review by a specific state department are Idaho, Mississippi, Nebraska, North Dakota, South Dakota, and Wyoming.

(NCQA), a private body that accredits HMO's expanded its accreditation standards to require plans to make available independent review of medical necessity denials.

The Supreme Court decision in *Rush Prudential vs. Moran* (June 2002) opened the door to more extensive state regulation of Health Maintenance Organizations (HMO's). Historically, states, not the federal government, have regulated insurance. However, state regulations failed to protect employees from loss of pensions; so in 1974 Congress enacted the Employee Retirement Income Security Act, (ERISA).⁴ To achieve national uniformity, ERISA supersedes or "preempts" any state law that "relates" to an ERISA plan. (An ERISA plan is any plan created by a private employer, group of employees, or union, with a few exceptions, to offer pensions, health coverage, or other benefits to employees. More than 125 million Americans obtain health care financed by ERISA.)⁵ The preemption by ERISA limits the application of state laws in complicated ways, making it hard to predict whether certain laws protect all patients in a state. In *Rush Prudential HMO vs. Moran*, the question before the court was whether *Rush Prudential*, a fully insured ERISA health benefit plan, had to comply with state law and submit to independent review in accordance with the Illinois HMO Act, which requires binding independent review when an HMO disagrees with the decision of a patient's physician that a treatment is medically necessary. The Supreme Court ruled that the Illinois HMO Act is not preempted by ERISA. The decision indicated that the majority of state laws requiring independent review of benefit denials can be enforced against HMO's.

As a result of the proliferation of independent review mandates, the number of IRO's has grown tremendously. Currently, IRO's operate in all 50 states.

Benefits of Independent Review

In November 1998, when independent review was still primarily state regulated and called "external review", the Institute for Health Care Policy, Georgetown University, completed a comprehensive overview of independent review programs as they existed at that time; independent review had been established in thirteen states and by Medicare.⁶ Among the findings:

1. Patients seek independent review of a wide range of health plan decisions, from those involving specialty care to those involving routine care such as equipment and supplies, and from those involving "life threatening conditions" to those involving questions with regard to whether a proposed treatment was restorative.

NAIRO has developed and maintained a data base of state regulations and contact information pertinent to independent review.

⁴ The full reference is the Employee Retirement Income Security Act, 88 Stat 832, 29 U.S.C.1001-461.

⁵ Fronstin P. "Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the 2001 Current Population Survey". EBRI Issue Brief no. 240. Washington D.C.: Employee Benefits Research Institute, December 2001

⁶ Pollitz K, Dallek G, and Tapay N. "External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare", prepared for the Kaiser Family Foundation. (www.kff.org), November, 1998. Hereinafter this document is cited as "Kaiser Report, 1998."

2. Generally, independent review programs are cost effective.
3. Key elements of independent review are independent expertise and prompt action.
4. Independent review upholds health plan decisions about as frequently as it overturns them.
5. Independent review programs are widely regarded as valuable, fair, and useful in strengthening patient confidence in managed care. Regulators, IRO staff, and industry representatives alike reached this conclusion about the process. The fact that the outcome of independent review equally favored patients and plans was cited as both an indication of the need for the process and an as evidence of its objectivity and credibility. After the publication of the 1998 Kaiser report, many private health plans announced that they would voluntarily provide their enrollees access to independent review when payment for care was denied.⁷

Similarly, other reports have also identified significant and potentially wide reaching benefits of independent review. Once lobbied against by many health plans, independent review has gained a wide range of acceptance as ultimately benefiting both members and health plans. A 2001 report by the American Association of Health Plans, the trade association of health insurers, states, “For the consumers of American health care, the widespread enactment of independent medical review is perhaps the most important development of the past decade. Independent medical review... offers historic opportunities for improvement in the American medical care system”⁸ Eighteen health plans interviewed by the AAHP in the study praised the generally excellent credentials of independent reviewers and credited the emergence of independent review programs with:

- Increasing member satisfaction with health care coverage
- Enhancing health plan credibility with members
- Diminishing the perception that administrators rather than physicians are making coverage decisions

Confirming the finding of the 1998 Kaiser report, the 2001 AAHP study also found that appealed decisions encompassed a wide range of issues, including:

- Disagreements about medical necessity
- Newly popularized treatment options
- Cosmetic surgery

⁷ Among the plans announcing their intention were Aetna US Healthcare, United Healthcare, HealthNet, PacifiCare Health Systems, and the California Association of Health Plans.

⁸ American Association of Health Plans, “Independent Medical Review of Health Plan Coverage Decisions: A Framework for Excellence”, April 2001. Hereinafter this document is cited as “AAHP 2001 report”. Subsequently, AAHP and HIAA (Health Insurance Association of America) merged to form AHIP (Association of Health Insurance Plans).

- Out of network specialists
- Requests for services in excess of plan limits
- Requests for experimental and investigational treatments
- Requests for non formulary drugs
- Requests for surgery when the patient has not yet tried a less invasive alternative
- Requests for services expressly excluded by contract
- Durable medical equipment and supplies
- Nursing home care
- Diagnostic testing
- Inpatient hospital stays
- Emergency room visits
- Ambulance transportation
- Home health care
- Mental health and/or substance abuse treatment
- Hospice care

Also confirming another finding in the 1998 Kaiser report, in tracking and analyzing IRO outcomes for independent “external” review, the 2001 AAHP study found that the IRO decisions split about evenly in favor of patients/providers and the health plans. In addition, independent review was found to have had a positive influence on health plans’ internal review processes, such as accelerating time frames for review and bringing in more external specialists for reviews of complex cases.

The AAHP report concluded that independent medical review makes health plans accountable to their members and can serve as an important tool in bridging the gap between the best available medical knowledge and the actual practice of medicine. “By providing reassurance to consumers that their health plans are held accountable to provide benefits consistent with the terms of their health coverage, and by providing decisions by independent physicians quickly and efficiently, independent medical review has the potential to significantly improve the health care system for American consumers.”⁹ Specifically, the report stated, “Properly executed, independent review organizations can become a critical part of the infrastructure that promotes the integration of the best scientific evidence into the current practice of health care. The continuous feedback provided by IRO’s is likely to play an important role in shaping health care decisions in (many) areas. The extent by which IRO’s operate by uniform standards, applying the best medical evidence to their reviews, will be reflected by America’s health plans in their coverage policies and their internal processes.”¹⁰ Consistent with this assertion, an earlier follow up Georgetown University Institute for Health Care Research and Policy (2000) found that state regulators are using aspects of independent review to address other problems in the health care system.¹¹ One state has incorporated independent review into its market conduct examinations. Others are using the

⁹ AAHP 2001 report at 7

¹⁰ Ibid at 7-8

¹¹ Dallek G and Pollitz K. “External Review of Health Plan Decisions: An Update”, prepared for the Kaiser Family Foundation (www.kff.org), May 2000. Hereinafter, this document is cited as “Kaiser Report, 2000.”

independent review process for quality improvement. A few states have tied the independent review process to the right of plan members to sue for malpractice.

Two more recent studies of independent review in California support earlier Kaiser Report and AAHP findings with regard to the percentage of cases in which independent “external” review upheld or overturned the health plan decision. The Institute for Medical Quality (2003) found that, over the time period in which medical review has been available in California, the review overturned health plan medical necessity based denials 60 per cent of the time.¹² (Appeals for independent review of experimental/investigational treatment were overturned in 36 per cent of cases.) The IMQ researchers noted, “During the time that independent medical review has been studied, it has generally been viewed as an effective mechanism for resolving disputes between patients and health plans...Plans have pointed out that independent medical review reduces perceptions of bias and may help reduce liability. Independent medical review is relatively cost effective, quickly accomplished, and provides a forum where medical professionals make medical decisions. It is seen as an important patient protection, giving consumers access to treatment, expertise, and services that they might not otherwise have...Independent medical review has the potential to assure (patients) that a sound decision was made because their request was evaluated by independent and well qualified experts.”¹³ In a 2004 peer reviewed study of independent review in California, independent review upheld the health plan decision in 58 per cent of total cases and overturned it in 33 per cent of total cases.¹⁴ Nine per cent of disputes were withdrawn for a variety of reasons. Among cases in which care was deemed experimental, 77 per cent of denials were upheld, compared with 53 per cent in reviews of medical necessity decisions. According to the authors, the findings suggest that the independent review process “adds a layer of patient protection to health plans’ coverage decisions...(the) additional patient protection appears to justify the investment most states have made in it.”¹⁵

Beyond added patient protection, cost effectiveness, and positive impact on health plan review processes and other health care management activities, an additional benefit of independent review is reduction of costly litigation. States with mandatory independent review laws can expect reduced litigation. As reported by the *New York Times*, “The theory is that external (independent) review will give patients a fair hearing and wipe out the need for most litigation...The experience of states in which mandatory external review has been tried, including New York, New Jersey, and Connecticut, confirms these expectations. When the external review sides with the patient, the plans almost always back down, unwilling to bear the legal risk of continuing to deny coverage for the disputed treatment. When the external review sides with the health plan, few

¹² Silverman J Kaufman E, and Barry T. “Independent Review Experiences in California, Phase II: Cases Including Medical Necessity”, prepared for the California Health Care Foundation by the Institute for Medical Quality (IMQ), April 2003. Hereinafter, this document is cited as “IMQ 2003 Report”.

¹³ Ibid at 12

¹⁴ Chuang K, Aubry W, and Dudley RA. “Independent Medical Review of Health Plan Coverage Denials: Early Trends” *Health Affairs* Vol.23, No.6, 163-9

¹⁵ Ibid at 14

patients or their lawyers waste time and money going before a jury to argue against a plan that has won approval from independent physicians.”¹⁶

Challenges to Independent Review

As the role, reach, value, and importance of independent review grows, the members of NAIRO believe that a number of factors threaten the integrity and the viability of the IRO process. Some of the same studies that identified the multiple benefits of independent medical review also found factors that challenge the independent review process. The most frequently noted challenges are barriers to patient access, variability in review methodology among IRO’s, driven by variability in regulatory specifications and client needs and preferences, and complex state regulations and inconsistency across states.

The 1998 Kaiser Report found that patients seek independent review infrequently. At that time, in Medicare, independent review was performed at a rate of about two cases per 1,000 managed care enrollees per year.¹⁷ In large states with established independent review programs, independent reviews were performed at a rate that is only a tiny fraction of Medicare’s. The 1998 Kaiser Report examined potential barriers to patient access to independent review as one possible reason to explain the infrequent use of these programs. State regulators frequently cited lack of public awareness about independent review. The length of the entire appeals process—from initial denial through levels of appeal and then to final independent review—may lead to patient attrition. And pursuing an independent review is often difficult. Patients who are struggling with serious illness or disability often need assistance in navigating the entire appeals process. A growing number of states have created health care ombudsman offices to help people with this process.¹⁸ State regulators have credited these efforts with effective “early intervention” that has helped to minimize the need for independent review at the state (external) level.

Increasingly, health plans have also engaged in “early intervention” by voluntarily providing their enrollees access to independent review when payment for care is denied. URAC accreditation of IRO’s has encouraged their use by health plans to provide independent review at levels of review and appeal offered within the health plan (commonly referred to as “internal” review.) In the summer of 2005, URAC and NAIRO conducted a survey of all IRO’s to identify current industry practices.¹⁹ The survey found that 73 % of the responding IRO’s provide state regulated “external” independent review. The same percentage indicated that they provide “internal” second level appeal independent review. Sixty percent provide “internal” first level appeal independent review and 53 % perform independent review of predetermination/ precertification

¹⁶ Weinstein M, “Will Patients’ Rights Fix the Wrongs?” *The New York Times*, June 24, 2001

¹⁷ Kaiser Report, 1998, at 6

¹⁸ At the time of the Kaiser Report, 2000, Connecticut, Florida, Illinois, Maine, Maryland, Massachusetts, New Mexico, Rhode Island, Texas, Utah, Vermont, and Virginia had established health care ombudsman offices to educate the public about health care rights and responsibilities and to help patients obtain answers to questions about their health care plans and their right to independent review. Since then, many states have established similar offices.

¹⁹ *URAC 2005 Medical Management Report* at 1. Please see attachment 1 for a definition of terms

decisions. The same survey found uniform agreement about what makes a review *independent*, regardless of whether the review is “internal” to a payor or “external” (state regulated). An independent review is *free from financial or relational conflict of interest*. The requestor/purchaser *does not select the peer reviewer*. The independent review is *advisory and consultative*, that is, it is *not a determination of benefits*. There are fundamental and critical differences between *independent review* and *utilization management*. URAC defines the latter as “the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provision of the applicable health benefits plan; sometimes called “utilization review”.²⁰ Unlike utilization management, independent review is *not* a coverage decision or a determination of benefits, and is *not* performed by a reviewer affiliated in any way with the health plan—regardless of whether or not a plan seeks independent review at its own “internal” decision making levels. **It is NAIRO’s position that utilization management requirements should not apply to IRO’s.**

The fact that IRO’s may perform independent reviews at levels “internal” to a health plan poses potential conflicts of interest for IRO’s. The URAC IRO accreditation standards prohibit conflict of interest in the independent review process for both the independent review organization and the individual reviewers who consider a particular case. The standards define conflict of interest as “any relationship on the part of the independent review organization or a reviewer that could compromise the independence of objectivity of the independent review process. Conflict of interest includes, but is not limited to: an ownership of interest of greater than 5 % by 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 product or service, a known familial relationship, (or) any prior involvement in the specific case under review.”²¹ The 2005 URAC/NAIRO survey found that overwhelmingly, URAC accredited IRO’s have developed processes to determine whether a conflict of interest exists and how to resolve it.²² For example, in the majority of instances, if an IRO had performed “internal” independent review for a health plan, it would not perform “external” (state regulated) independent review for the same case. Also, the IRO would not request that the same reviewer consider the case at more than one level of “internal” independent review. In addition, URAC accredited IRO’s require that their reviewers identify situations in which the reviewer may have a conflict of interest, such as a pre-existing relationship with the patient’s health care provider, a professional bias in relation to the proposed treatment, a pre-existing relationship with the payor/purchaser of the review, a pre-existing relationship with the patient or family, or a financial interest in the proposed intervention. According to the 2005 URAC/NAIRO survey, in the rare (1%) of cases in which IRO’s encounter conflicts of interest, the most frequent was a pre-existing relationship between the reviewer and the provider whose case was under review. In these or other conflicts of interest, 93% of the organizations who responded would deal with the conflict by declining the case, 93 % by reassigning to another reviewer, and 57% by referring the

²⁰ Ibid.

²¹ URAC *Core Standards, Version 1.1* and *Independent Review Standards, Version 2.0* at 2

²² URAC *2005 Medical Management Report* at 1

case to another company.²³ **Because of the consistency and stringency of the URAC accreditation standards with regard to conflict of interest, as well as needs to streamline the accreditation process, NAIRO advocates that states adopt URAC certification in lieu of state certification.**

Across states and across health plans, there is still much variability around how medical necessity is defined, and who defines it. The definition of “medical necessity” is often the determining factor in independent review of cases in which the treatment at issue has been deemed “experimental or investigational”; many plans will not cover “experimental or investigational treatment” unless it is found to be “medically necessary”. For state regulated (“external”) reviews, depending on the state, “medical necessity” can be defined by the state, the independent reviewer, or the health plan. Thirty five states define in law or regulation a standard of medical necessity that independent reviewers should follow in evaluating cases.²⁴ However, the definition may be the state’s own definition, medical necessity as defined by the plan, or medical necessity as defined by the reviewer/IRO, whose definition then “trumps” that of the plan. States vary widely in specifying what the IRO must consider in rendering its findings (See Table 1)²⁵ At least 33 states specify that the independent reviewer consider plan language, 27 specify consideration of plan criteria, the same number require consideration of prior appeals, 28 require consideration of scientific evidence (such as peer-reviewed studies and/or nationally accepted practice guidelines), and 26 specify that the reviewer’s independent judgment should be a factor. Who defines “medical necessity” and how independent reviewers interpret that definition can determine the outcome of any appeal. Plans and purchasers of independent review services argue that if non plan definitions of medical necessity are used, they will lose their ability to meaningfully determine what is and what is not a covered benefit. Patient advocates counter that independent review is designed to resolve disputes over what is and is not medically necessary; therefore, this definition should not be controlled by one of the disputing parties.

As the result of persistent variability in regulatory specifications and in health plan needs and preferences, there is a corresponding variation in review methodology across IRO’s, as the 2005 URAC/NAIRO survey illustrates. When asked, to identify, by percentage of cases completed in 2004, the primary methodology used for “internal” and for “external” review, the leading responses among IRO’s for “internal” review were

²³ IRO’s use more than one method of handling conflict of interest; therefore the total of responses is greater than 100%.

²⁴ Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Maryland, Michigan, Minnesota, Missouri, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wisconsin. Data obtained primarily from two sources: Kaiser Report, 2000 at 11 and the State Statutory and Regulatory Database, NAIRO, completed 2005, proprietary, hereinafter *NAIRO Statutory and Regulatory Database*

²⁵ Data obtained primarily from two sources: *NAIRO Statutory and Regulatory Database* in 23 and Mariner WK, “Independent Review of Health Maintenance Organizations’ Medical Necessity Decisions”, *The New England Journal of Medicine*, Vol. 347 (26), December, 2002

criteria based (46%), practice guideline based (38%), and evidence based (38%).²⁶ The leading responses for “external” review were 53% for evidence based reviews, 48% for criteria based reviews, and 38 % for practice guideline based reviews. Across organizations responding, a small but substantial number of reviews were performed for the purpose of benefit interpretation. The survey also asked, “For your organization’s 2004 cases, who or what determined what reviewers used as the *primary* basis of his or her findings, and in what percentage of cases?” Here, client preference was the leading determinant of the primary review basis for “internal” review (70%) and regulatory requirement was the leading determinant of the primary review basis for “external” review, closely followed by client preference (61%). **NAIRO advocates the consistent adoption of a medical rather than legal decision making model, employing the best available medical evidence as a basis for independent review decision making.**

In addition containing widely diverse direction in defining the basis for medical necessity, the laws and regulations between states, pertaining to “external” independent review, vary significantly in a number of other ways:

1. Whether the decision is binding on the health plan, the enrollee, or both
3. Whether the IRO is required to disclose the identity of the reviewer
3. Whether there are provisions for immunity for the IRO, the reviewer, or both.

These variations are represented in Table 2.²⁷ In the majority of states (39), the independent review recommendation is binding on the health plan. In fewer states (19), the independent review finding is also binding on the enrollee. In a small number of states, the IRO must disclose the identity of the independent reviewer. Twenty nine states provide legal immunity to IRO’s for their good faith efforts, 31 provide immunity to the independent reviewer, and 28 provide immunity to both. While revealing the identity of the reviewer in rare situations may have value, it is NAIRO’s position that **in almost all cases, reviewer anonymity is essential for the integrity of the review process.** Further, IRO’s and their experts essentially perform a peer review activity – a good faith determination based on the documentation and information provided to them. **NAIRO recommends that all states provide statutory immunity for IRO’s and independent reviewers for all review activities conducted in good faith.**

RECOMMENDATIONS FOR IMPROVEMENT

To promote and enhance the value and consistency of independent review, and to preserve its integrity, NAIRO recommends the above noted and additional improvements for consideration by legislators, regulators, and health plans:

1. Accept URAC Independent Review Organization (IRO) Accreditation in Lieu of State Certification

²⁶ *URAC 2005 Medical Management Report* at 1. The percentages do not equal 100% because IRO’s identified combined methodologies as the primary methodology in many cases. See glossary (Attachment 1) for a definition of terms.

²⁷ *NAIRO Statutory and Regulatory Database* at 23; *Mariner WK* at 23.

In addition to passing independent review legislation, 44 states and the District of Columbia have also established extensive application requirements. Much of the required information is both similar from state to state and similar to that which URAC requires. However, states request this information in formats that vary somewhat, sometimes only slightly. The result is a costly and unnecessary compliance burden, which in some instances inhibits an accredited IRO from seeking licensure in some states. As noted above, URAC accreditation standards are extremely high with regard to conflict of interest. They are also stringent concerning telephone access, reviewer credentialing and qualifications, case processing, and decision notice. In many cases, the URAC standards exceed state certification requirements. NAIRO recommends that states accept URAC certification information in URAC format and ask only for application information that goes beyond the URAC accreditation process.

2. Provide Statutory Immunity for IRO’s and Reviewers for Activities Conducted in Good Faith

As noted above, independent review is a consultative, advisory activity. It is not the practice of medicine; reviewers do not evaluate or treat the health plan member. In addition, fees paid for independent review are not commensurate with any assumption of medical risk liability. The cost of independent review would rise dramatically if independent reviewers were held medically liable for any “internal” or “external” review findings. NAIRO supports providing immunity for IRO’s and for reviewers for independent review activities.

3. Base Independent Review on the Best Available Medical Evidence; Adopt a Medical Rather than Legal Decision Making Model

As noted above, there are notable differences between states in requirements for what an IRO reviewer is to consider in performing an independent review. This leads to inconsistent application of the best available medical evidence. It is NAIRO’s experience that reviews based primarily on independent judgment/clinical opinion yield wide variations in outcomes that negatively impact the integrity and value of the independent review process. A reviewer significantly strengthens his or her decision by basing it on current peer reviewed research studies or nationally accepted practice guidelines. By clearly stating the basis for his or her decision, the expert reviewer enables the health plan to evaluate – and when appropriate to modify – its own internal policies. NAIRO recommends a medical evidence basis for all independent review activity; particularly for state regulated “external” reviews, which, in the majority of states, are binding on the health plan. The “final” stage of review should rely on the most robust methodology available, especially when independent review serves as an alternative to litigation.

In addition, some requests for independent review, both “internal” and “external”, limit the scope of the review to whether, in making a decision, the health plan or utilization management entity adhered to the review criteria it cited as a basis. This is a legal rather than a medical decision making model. While answering this question “yes” or “no” does not make a review less independent (as defined above), the narrow scope of

the review question is problematic. The health plan criteria may be outdated. Also, reviewers are not likely to address relevant evidence based medical necessity issues, for example: Is there established benefit to the proposed treatment? Is it likely to be of greater benefit than standard care? Are there compelling issues not addressed by the criteria that are relevant in this case?

The members of NAIRO believe that all independent reviews should employ a medical rather than legal decision making model and that they should incorporate the best available scientific evidence. Independent reviews should be supported by, or at least show that the reviewer considered, such credible sources as current peer reviewed clinical studies, reviews of multiple related studies, and/or other sources that reflect emerging scientific opinion and consensus.

4. Eliminate Same State Licensing Requirements for Reviewers

One extremely troublesome development is the requirement by various states that the physician who conducts the independent review must be licensed where the patient resides.²⁸ Requiring same state licensure could result in review determinations based more on regional practice patterns than on medical evidence or nationally accepted practice guidelines. Same state licensure requirements also increase the possibility of conflict of interest. For example, the reviewer might know, or have a professional relationship with one of the providers caring for the patient. The two may refer patients to one another, or a potential referral potential may exist. They may have attended the same medical school or have a mentor or colleagues in common.

In addition, it would be prohibitively costly for IRO's to recruit and credential physicians in each state representing the full spectrum of specialties required to perform true peer reviews. According to the 2005 URAC/NAIRO survey, at least 6 accredited IRO's are not accepting cases for independent review in states with same state licensure requirements. NAIRO recommends that same state licensure requirements be eliminated.

5. Guarantee Anonymity for Reviewers

In some rare situations, revealing the identity of the reviewer might have value. For example, it may be helpful for the patient's treatment if consultation between the expert reviewer and the patient's provider takes place. However, even in these rare circumstances, disclosing the identity of the reviewer has the potential to compromise the independence and the integrity of the review. Managed care companies and their members are best served if the reviewers can disregard personal and professional considerations in order to complete a completely independent review opinion. These considerations include potential referrals, future advancement, and relationships within medical societies and organizations. In addition, as the appeal process progresses, many patients and their families increase their emotional investment in the outcome. They may

²⁸ According to the NAIRO Statutory and Regulatory Database and other current NAIRO information, states that require same state licensure for reviewers are: Hawaii, Kansas, Mississippi, Missouri, Montana, New Jersey, and New Mexico. The District of Columbia has the same requirement.

be committed to “the cause” and volatile in the face of a decision with which they disagree. A reviewer whose identity is revealed can be subject to harassment or even threats to his or her safety.²⁹

6. Recognize that independent review is not utilization management. Therefore, IRO’s should not be required to seek licensure or the equivalent as utilization management entities.

The fundamental differences between independent review and utilization management are outlined above. Despite these critical distinctions, a number of states still require organizations whose sole business is independent review to be licensed or certified as a utilization management entity. These mandates are in part the result of the retention of dated “utilization review” regulations that have not evolved to keep current with the state of the medical management industry. While many IRO’s also provide utilization management services, these are offered as a *distinct* service; in addition, URAC accredits utilization management according to a set of standards distinct from those applied to independent review.³⁰ Because they are not utilization management entities and do not possess the programmatic elements of utilization management organizations, IRO’s cannot comply with utilization management oriented regulations. For example, utilization management entities are required to use standards and criteria for making coverage decisions, and they must submit these as part of some state applications. IRO’s do not make coverage decisions, nor do they generate or “select” criteria. The role and purpose of an IRO reviewer is to bring the weight of medical evidence and best practices to bear on information provided about a patient’s clinical presentation. Without providing standards and criteria, IRO’s are unable to qualify for certification in some states. As a result, in those states, health plans and consumers have narrower options available to them for independent review. Rather than requiring IRO’s to be certified as utilization management entities, states could: 1. Adopt URAC’s accreditation standards for IRO’s (See #2 below). 2. Amend statutes and regulations to provide for consultative input by an IRO to the health plan or utilization management entity.

7. Accept IRO Credentialing of Reviewers in Lieu of Individual States’ Requirements

URAC’s credentialing requirements for reviewers are very similar to those established by the National Committee on Quality Assurance (NCQA) for providers delivering direct patient care. For example, in accordance with URAC requirements, accredited IRO’s already conduct extensive background checks to determine a reviewer’s qualifications and his or her ability to perform a knowledgeable, defensible review. These

²⁹ Though rare, overt threats by dissatisfied patients and their providers have occurred. In one particularly disturbing case shared with NAIRO, the reviewer received a threatening phone call after she concurred with the health plan’s finding of lack of medical necessity. The caller possessed specific knowledge of the location of the reviewer’s practice and home location.

³⁰ *URAC 2005 Medical Management Report* at 1.

checks include verification of the reviewer's training, education, professional licensing, malpractice history, and Drug Enforcement Agency (DEA) number and hospital privileges when applicable. Accredited IRO's also require reviewers to disclose any potential or actual conflict of interest. These include: professional, financial, or familial affiliations that involve the ownership of 5% or more of the shares of a company producing or selling pharmaceuticals, biologicals, medical devices and /or other medical technologies; ownership of 5% or more of the shares of a hospital, hospital system, surgical center, ambulatory center, diagnostic center, health plan, and/or health insurer; research funding, a percentage of sales and/or payment as a consultant for any pharmaceutical, medical device, and/or biotechnology manufacturer; receipt of 50% or more of compensation from a specific health plan, insurer, and/or hospital, hospital system, or independent practice association; holding a board seat, officer's position, or senior administrative position with a hospital, hospital system, health plan, health insurer, pharmaceutical biotechnology company and/or medical device manufacturer; research interests that might create a conflict of interest; or any other potential or actual conflict of interest that could have a bearing on independent case review.

As part of their application processes, some states require extensive (6 to 12 page) biographical affidavits for each reviewer. Some require that the affidavits be notarized. Others require 10 year work and residency requirements and some even require height, weight, and eye color. These requirements not only duplicate the credentialing process already required by URAC; they are intrusive and request information irrelevant to the expert's qualifications and abilities as an independent reviewer. These requirements are unduly burdensome for an IRO, who may have contract with hundreds of physicians and other clinicians. It is also an unwarranted burden for the individual reviewers. NAIRO recommends that state accept IRO credentialing of URAC accredited IRO's as fully satisfying state requirements.

8. End the Exclusion of Single Specialty IRO's

Many IRO's contract with a full range of specialists to serve as reviewers. However, other fully accredited IRO's focus on particular clinical fields. For example, one NAIRO organization is a single specialty company that performs primarily behavioral health and addictions medicine reviews. As such, it offers a strong panel of expert mental health reviewers.

Some states will not certify an IRO unless it can offer a full range of specialty reviews, even though specialty IRO's bring a solid depth of expertise to the IRO field.³¹ States whose regulations have denied certification to specialty IRO's have indicated that they assign state regulated "external" review cases to IRO's on a rotating basis, such that each IRO must be able to handle any case assigned to it. Other states have developed rotational methods that include single specialty IRO's, showing that exclusion of such IRO's need not be a practical or procedural necessity. If a specialty focused IRO

³¹ States that will not certify single specialty IRO's include Colorado, Georgia, Kentucky, New Jersey, New York, and Washington.

otherwise meets a state's certification requirements, the IRO should be included in case assignments. In addition, to bar single specialty IRO's is an unreasonable restraint of trade. NAIRO recommends ending the exclusion of single specialty IRO's.

CONCLUSION:

The members of NAIRO believe that by adopting the recommendations in this paper, legislators, regulators, and health plans will increase the quality and value of independent review at all levels, promote its integrity and consistency, and improve the quality of health care. Representatives of NAIRO are available to discuss their experience and provide suggestions for improving medical review. For more information, contact Harry Feder at (516) 326-7767 or via e-mail at hfeder@ipro.org.

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GLOSSARY OF TERMS:

External Reviews: State-mandated reviews performed by an Independent Review Organization (IRO). These clinical reviews are determinant in coverage disputes involving medical necessity, medical appropriateness, proven benefit (experimental/investigational) and other issues dealing with medical judgments. External reviews are the final appeal (often the third appeal). Most states require that health plans use a vendor selected by the state.

Internal Reviews: The first and second clinical reviews performed in conjunction with an initial and/or second appeal of a non-coverage decision based on medical judgment

(medical necessity, medical appropriateness, experimental/investigational and other decisions based on medical judgment). These reviews may be performed by physicians and other clinicians employed or contracted by the health plan or by an Independent Review Organization (IRO). They include clinical reviews for self funded health benefit plans, governed by ERISA and regulated by the Department of Labor. When an IRO is used, the health plan claims administrator or utilization management organization does not select the clinician reviewer. The reviews performed by an IRO as part of the internal review process are advisory, not determinant.

Peer Review: Specialty-matched reviewers. These reviews occur at all levels of review.

Pre-determination Review: Reviewer considers the health benefit plan, proposed health service and patient-specific information in advising the health plan/claims administrator/care management organization regarding coverage prior to a coverage determination.