NAIRO Comments on Interim Final Rules (IFR)
Related to Internal Claims & Appeals Conflict of Interest
Section 2719 – Patient Protection & Affordable Care Act

INTRODUCTION

This document has been prepared by the National Association of Independent Review Organizations (NAIRO) in response to the request for public comment on the Interim Final Rules issued by the United States Department of Health and Human Services (DHHS), the Department of Labor (DOL) and the Treasury (IRS) (collectively "the Departments") on internal claims and appeals and external appeals for group health plans and health insurance issuers under the Patient Protection and Affordable Health Care Act (PPACA) Section which amended the Public Health Service (PHS) Act Section 2719.

ABOUT NAIRO

NAIRO is a collaborative group of 19 companies located in 14 states that provide independent medical reviews which are at the core of the internal and external appeals processes. NAIRO members are all accredited by the Utilization Review Accreditation Commission (URAC) to provide objective standards-based determinations which are free of conflict of interest. NAIRO is recognized as a leading authority on the independent review process, and is regularly consulted by industry groups, accreditation agencies and government bodies on issues of public policy and best practices. NAIRO members are the nation's leading IROs, are deeply involved in managing the internal and external appeals process for a majority of America's health insurance payment system, both private and public. See www.nairo.org for additional information.

EXECUTIVE SUMMARY

The purpose of Public Health Service (PHS) Act Section 2719 and these rules is to "ensure that plans and issuers implemented more uniform internal and external claims and appeals processes and to set a minimum standard of consumer protections that are available to participants, beneficiaries, and enrollees." The fourth requirement for these Interim Final Rules (IFRs) is to provide new criteria with respect to avoiding conflicts of interest (COI).

NAIRO's concern is that the IFRs implementing Section 2719 regarding the internal appeals process do not adequately protect patients from conflicts of interest. As currently drafted, the IFRs do not preclude health plans from reviewing appeals of their own adverse coverage determinations using in-house clinicians, thus creating a conflict of interest. Use of in-house clinicians does not protect the rights and health of consumers in the spirit of the health care reform legislation.

NAIRO recommends that the conflict of interest section of the IFR be modified to preclude health plans from using their own employee clinicians to review internal level appeals of adverse determinations for the following reasons:

1) **In-house employee clinicians are inherently conflicted because they are wedded to the success or failure of the company and remain subject to the health plan management directives**.

2) **Patients benefit from evidence-based determinations and the application of the latest medical science but it is generally accepted that most health plans do not have access to the appropriate type of specialist clinician to adequately review the subject matter of the appeal.** As a result, plans instead may need to use clinicians that are not expert in the subject matter of the appeal. This both disserves - if not ultimately harms - the patient and creates inefficiencies for the payor.

3) **Unbiased, accurate appeals ensure consumers get the coverage they pay for and expect under their contract.** By using in-house clinicians as reviewers, health plans can appear biased or "denial driven" and more concerned about their bottom line than utilizing evidence-based means to select the latest medical services and technologies to improve patient outcomes. This perception may diminish consumers' confidence in plans' medical determinations and further reduce consumers' use of the appeals process.

4) **Use of Independent Review Organizations for Internal Appeals is a Best Practice.** Many leading national health insurance companies and administrators of self-insured plans have already adopted the use of Independent Review Organizations (IROs) for their internal appeals process as a best practice and to avoid the appearance of COI when issuing adverse benefit determinations upon appeals by members.

5) **Payors save money and time when the right, evidence-based decision is made in the first instance.** IROs help health plans manage costs by reducing overutilization as well as unnecessary external appeals. This also saves critical time for consumers in need of urgent treatment, which improves quality of care.

6) **Policymakers Already Recognize the Value of Rigorous COIs Requirements:** States, the National Association of Insurance Commissioners (NAIC), the Department of Labor individually, and the Departments (DOL, HHS, Treasury) through this IFR's section on external appeals, recognize the importance of strict conflicts of interest requirements for external reviews, and internal appeals should be held to the same standards to protect consumers in the spirit of the health care reform legislation.

ANALYSIS OF CONFLICTS OF INTEREST STANDARDS AS PROPOSED IN THE IFR

The Interim Final Rules set a very low standard as it relates to the avoidance of conflict of interest by health plans when conducting internal appeals. The only standard that is mentioned relates to the hiring, compensation, termination or promotion of individuals, or the contracting of experts based on their reputations.

Below is a list of conflict of interest standards that are specifically not covered, and which should be added to the regulations:

- Reviewers of internal appeals should not be employees of the health plan;
- Reviewers of internal appeals should not have been involved in making the initial determination of denial of benefits; and

- Reviewers of internal appeals should be accredited by URAC or another recognized body to perform independent review and be bound by the conflict of interest standards of that accrediting body.

NAIRO believes that these additional requirements would set the minimum standards that are necessary to ensure that health plan internal appeals adhere to the intent of the healthcare reform legislation. As explained in detail below, all stakeholders benefit from adopting rigorous COI standards and there is precedent for doing so for internal as well as external appeals.

REASONS TO REQUIRE RIGOROUS CONFLICTS OF INTEREST STANDARDS FOR INTERNAL APPEALS

The Departments' proposal that health plans will "avoid conflicts of interest" in internal appeals if health plans ensure that "*hiring, compensation, termination, promotion or other similar decisions about any individual (such as a claims adjudicator or medical expert" are not "based upon the likelihood that the individual will support a denial of benefits*," is simply not rigorous enough to prevent conflicts of interest as the rule does not prohibit health plans from using their own clinicians for internal appeals. In-house clinicians are inherently conflicted; their livelihood is wedded to the success or failure of the company, and they remain subject to the health plan's management directives, including corporate cost containment directives and corporate practices and policies. This inherent conflict can and – and as explained in detail below - should be avoided by prohibiting health plans from using in-house clinicians for internal appeals.

1. <u>All Stakeholders Benefit from Rigorous Conflict of Interest Standards for Internal Appeals as Applied through Use of IROs</u>

Use of Independent Review Organizations (IROs) accredited for internal appeals provides benefits to both consumers and payors. Accredited IROs must comply with the strict conflicts of interest standards[1] and as such, these IROs ensure that consumers receive the protections intended under the health care reform legislation, PHS Act Section 2719, NAIC's Model Act, ERISA, and state external review laws. For payors, use of IROs for internal appeals reduces costs and improves operational efficiency.

Initially, IROs were formed in response to states' Patients' Bill of Rights laws that afford patients a right to an external independent review of a health plan's decision to deny, reduce, or terminate care. URAC-accredited IROs, like those involved in NAIRO, review healthcare claims based on current medical literature, technology and generally accepted clinical practice guidelines. Independent review by IROs is widely cited as a fair, impartial, and expeditious and cost effective way to resolve disputes at all appeal levels.

A. <u>Improved Patient Outcomes through Evidence-Based Determinations and Application of the Latest Medical Science:</u> IROs provide a mechanism for quickly and consistently applying expert knowledge to claims decisions and ensuring consumer protections and rights are afforded, leading to improved

[1] URAC, the only national accrediting body for IROs, requires strict COI measures for IROs and their expert reviewers. S*ee URAC IRO standards #6 – 8.* These URAC IRO standards assure that organizations that perform this independent service are free from conflicts of interest and establish qualifications for physician reviewers. URAC IRO COI standards are modeled after NAIC's COI measures. URAC accreditation is the gold standard for IROs. An organization with this URAC IRO accreditation is bound by a commitment to follow a fair and impartial review process that benefits both consumers and health insurance payers.

patient health outcomes. Information and scientific advancements in the medical field are increasing at unprecedented rates. Medical disciplines fragment into new specialties every year. Then those specializations fragment again. This means medical directors and claims managers need access to outside medical knowledge beyond their expertise and their internal clinician resources. IROs have timely access to specialized medical resources that payers cannot afford or to which they have limited and/or untimely access. Due to the depth of expertise in an IROs' specialist network, and the volume and breadth of claims it reviews on a daily basis, IROs are better equipped to review the wide variety of patient claims than in-house clinicians. IRO experts are on the cutting edge of medical services, treatments and devices. This expertise is advantageous for all stakeholders, particularly to consumers from a COI standpoint. Additionally, NAIRO supports a same or similar specialty threshold for reviewers. This is something that is required by URAC, the States and the NAIC Model Act. It ensures that the appropriate type of clinician performs the review.

IRO expert reviewers allow payers to make evidence-based healthcare determinations for patients. These reviewers can often better determine the medical necessity or the experimental/ investigational nature of a procedure than the plan's physician reviewer or the case administrator. Frequently, IRO decisions help expand health coverage for procedures that should be covered as the current standard. Bariatric surgery is a good example of an advanced surgical procedure that was widely excluded from coverage five years ago, but which is now routinely covered and considered to be an effective treatment for morbid obesity.

B. Enhanced Consumer Protection from Unbiased, Accurate Appeals: A recent America's Health Insurance Plans (AHIP) study proves that external review is woefully underutilized, as less than 1 in 10,000 eligible patients submit appeals for external review of coverage disputes.[2] Consumers are uninformed and/or do not understand their appeals options. This makes independent, conflict-free internal appeals all the more important for consumer protection, as internal appeals must typically be exhausted before patients can access external review processes.

Moreover, according to two studies[3], approximately 40-50 percent of the patients who challenge a denial from an internal appeal later get their coverage denial reversed when reviewed externally by an IRO. Given this high reversal rate and that patients must typically exhaust their internal remedies before seeking external review, the failure to adequately protect patients throughout the internal

[2] The Association of Health Insurance Plans 's(AHIP) report on state external review programs found that on average less than 1 out of 10,000 eligible individuals submitted appeals for external review of coverage disputes. Specifically, the appeal rate was approximately 0.94 appeals per 10,000 eligible health plan members. As evidenced by this study external review is woefully underutilized. AHIP Center for Policy and Research, "An Update on State External Review Programs," 2006," July 2008.

[3] In the same AHIP report, external reviewers upheld the original decision of the health insurance plans in 59 percent of cases. In 37 percent of cases, the reviewers fully agreed with the consumer who filed the appeal. In the remaining four percent of cases, the independent reviewers partially agreed with the consumer. Overall, the percentage of cases in which the decisions of the health insurance plans were upheld has been above 50 percent in each year of the AHIP study. Again, this high number of overturns can be attributed to the use of plan clinicians at the internal level that are not qualified to review the subject matter of the appeal.

review processes is especially harmful to patients as, in many cases, the delay in getting to an external appeal review renders the decision irrelevant due to the time-sensitive nature of many medical decisions. With only 1 in 10,000 consumers utilizing external review, 40-50 percent of denials which are reversed, how many consumers are being denied coverage to which they are rightfully/contractually entitled? This can be traced directly back to the use of in-house plan clinicians for internal appeals that are not qualified to review the subject matter of the appeal. Arguably setting a rule that allows inherently conflicted in-house clinicians to review internal appeals will not improve patients' confidence in or use of the external appeals process established to protect consumers.

C. Use of Independent Review Organizations for Internal Appeals is a Best Practice: Today, IROs are involved at all stages of the medical decision making process. Many leading health plans, third party administrators and utilization review organizations outsource their reviews of *internal* appeals to IROs. As discussed later in detail, this has been widely recognized as a best practice in states and the federal government, fully insured and self-insured markets, even if many health plans continue to use internal clinicians for such appeals.

D. Improved Efficiency for Payors: IROs help ensure that the right, evidence-based determinations are made in the first instance, which ultimately helps manage plan costs by reducing overutilization as well as unnecessary appeals. Using unbiased and same or similar specialty reviewers, IROs can help health plans decrease the cost of appeals and likelihood of litigation by helping to make the correct coverage determination and providing legally defensible claims. At the same time, IROs eliminate any COI concerns and help to ensure plan enrollees receive the coverage for which they contracted. Not only does the use of IROs help to eliminate conflict of interest issues in the spirit of health care reform, they provide a broader range of credentialed, licensed and actively practicing specialists focused on medical niches that health plan providers or payers may not have access to or cannot afford to employ.

   IROs improve payor efficiency by reducing administrative costs associated with internal appeals. As treatment costs, complexity and medical specialization increase, these factors may force claims managers to error on the side of paying unnecessary or questionable claims because they lack access to the same or similar medical expertise for making informed decisions within an acceptable timeframe. In such cases, outsourcing medical decisions to an IRO can eliminate unnecessary treatments and have a dramatic impact on lowering healthcare claims costs.

2. There is Precedent for More Rigorous COI Requirements

As explained below, holding internal appeal COI standards to the same COI standards as external appeals is not novel; indeed many leading health plans already do this as a best practice. Moreover, where the legislation's intent is to protect consumers, and consumers typically must first exhaust their internal appeals options before seeking external review, and where the Departments already recognize that consumers benefit from rigorous COI standards for external reviews – having adopted the consumer protections from the NAIC Uniform External Review Model Act (NAIC Model Act) for state external reviews as part of this Interim Final Rule – it would be consistent with the spirit of the health care reform legislation to require the same COI standards for internal appeals

A. Leading Health Plans Already Use Independent Review Organizations to Avoid COIs: While far from universal, most leading health plans long ago adopted the use IROs for their internal appeals process as a best practice and to avoid the appearance of COI when issuing adverse benefit determinations upon appeals by members. For example:

- Aetna recently has voluntarily implemented an independent review program for its commercial HMO, QPOS®, and USAccess® members, and for members of fully insured traditional based health plans. These reviews are performed by IROs; and
- Self-funded traditional health plan sponsors plans have a long-standing practice of using IROs to review internal appeals, a practice that was originally precipitated by ERISA regulations.

By using IROs for internal appeals, certain plans have made it a best practice to hold their internal appeals processes to the same COI standards as the external or third level appeals COI standards mandated by state laws.

NAIRO believes that the best practice of using IROs for internal reviews should be adopted universally by all health plans. Modifying Section 2719 to include this practice will ensure that consumer appeal rights are afforded full protection in the spirit of the health care reform legislation.

B. Policymakers Already Recognize the Value of Rigorous COI Requirements: Forty-four States, the National Association of Insurance Commissioners (NAIC), the Department of Labor individually, and the Departments (DOL, HHS, Treasury) through this IFR's section on external appeals, recognize the importance of strict conflict of interest requirements for external reviews. In order for health consumers to be fully protected under the health care reform legislation and to receive the health care coverage they contract for, internal appeals must be held to the same COI standards as external or third level appeals.

i. *Existing Department of Labor Regulations:* For more than ten years, the Department of Labor (DOL) has required more rigorous COI standards for group health plans' internal appeals than those currently proposed under this IFR. Since 2000, 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." 29 CFR § 2560.503-1(3)(ii). Leaving consumers *less* protected from internal conflicts of interest than before health care reform is both inconsistent with the intent of the Patient Protection and Affordable Care Act, and poor public policy.

While NAIRO believes these existing DOL regulations could be strengthened to require use of URAC-accredited IROs for internal reviews which would ensure internal reviewer independence and avoidance of COIs, at a minimum the Departments should not set a weaker COI standard than the one DOL already requires. Especially when considering the consumer protection goals at the core of PPACA, the Departments should require plans to

adopt the strongest standards to avoid COIs to improve upon existing regulatory standards, not weaken consumer protections through the new regulations.

ii. *Interim Final Rules – External Appeals*: In addition to setting standards for internal appeals, PHS Act Section 2719 also calls for a system for application of either a state external review process or a federal external review process. The IFRs set forth the minimum consumer protections, taken from the NAIC Model Act that must apply for a plan or issuer to be subject to a state external review process. There are 16 consumer protection standards set forth in the rules for an external review process and these are minimum standards, including the scope COI protections outlined below.

NAIRO believes the internal appeal COI standards should be held to the same level as the external appeal COI standards to ensure full consumer protections consistent with the spirit of the law. This will strengthen the integrity of the appeals process in the following ways:

- Consumers will receive statutory guarantees that all health plan's internal appeals process are objective, free from conflict of interest and based on the latest medical evidence and accepted standards of care;
- Consumer appeals will be adjudicated in a more timely fashion, leading to better quality of care;
- The overall costs associated with correctly handling consumer appeals will be reduced by ensuring objectivity at the earliest stage of the appeals process, and will be borne by health insurers themselves.
- State governments and consumers will not bear additional costs and time delays caused by over reliance on the External Appeals process to achieve a fair determination.

iii. *Existing Laws as Model of Appropriate COI Standards:* Currently, most states rely upon external review programs as a means to resolve coverage disputes between consumers and health insurance plans. External review programs provide a way to resolve disputes in a fair, timely, and less costly manner than through the courts. Currently, 47 states and the District of Columbia operate external review programs. These jurisdictions mandate independent external review by an IRO and independent, board certified reviewers in active practice in the same or similar specialty as the treating provider.

For example, under the recently enacted Health Carrier External Review statute, 50 Illinois Administrative Code 5430, reviewers must meet the following minimum standards to conduct external review:

i) Be an expert in the treatment of the covered person's medical condition that is the subject of the external review;

ii) Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition as the covered person;

iii) *Hold a non-restricted license in a state of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review; and*

iv) *Have no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical reviewer's physical, mental, or professional competence or moral character.*

The statute further requires that neither the IRO selected to conduct the external review nor any clinical reviewer assigned by the IRO to conduct the external review may have a material professional, familial or financial conflict of interest with any of the following:

i) *The health carrier that is the subject of the external review;*

ii) *The covered person whose treatment is the subject of the external review or the covered person's authorized representative;*

iii) *Any officer, director or management employee of the health carrier that is the subject of the external review;*

iv) *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 external review;*

v) *The facility at which the recommended health care service or treatment would be provided; or*

vi) *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 external review.*

The state external review laws' high level of reviewer independence and avoidance of COI is further supported by NAIC's Model Act, which was adopted in July of 2008. The Model Act serves as a guideline for independent external review also mandates review of third level appeals by an IRO. The purpose of the Model Act is to provide uniform standards for the establishment and maintenance of external review procedures to assure that covered persons have the opportunity for an independent review of an adverse determination or final adverse determination, as defined in this Act.

Under Section 13(b) of the Model Act, all clinical reviewers assigned by an independent review organization to conduct external reviews shall be physicians or other appropriate health care providers who meet the following minimum qualifications:

- *Be an expert in the treatment of the covered person's medical condition that is the subject of the external review;*
- *Be knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical condition of the covered person;*

- *Hold a non-restricted license in a State of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review; and*
- *Have no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that have been taken or are pending by any hospital, governmental agency or unit, or regulatory body that raise a substantial question as to the clinical reviewer's physical, mental or professional competence or moral character.*

Under the Model Act, Section 13(D), IROs and their reviewers are also subject to the same rigorous conflict of interest standards as the ones outlined above under 50 Illinois Administrative Code 5430.

NAIRO believes these reviewer independence and COI avoidance measures should be added to Section 2719 to ensure the health care consumers are afforded the protections intended under the health care reform legislation and the patient bill of rights.

CONCLUSION

The Patient Protection & Affordable Care Act lays out a broad vision for transforming our nation's healthcare system over the next several years. At the core of this legislation is the notion of consumer protection. The proposed changes to Section 2719 that are outlined in this document are submitted with the goal of ensuring the original intent of the healthcare reform is fulfilled. We urge HHS, DOL, and IRS regulators to carefully consider the expert viewpoint of NAIRO on this topic, given the deep involvement that NAIRO members have in adjudicating claims and appeals for our nation's health plans.