Affordable Care Act (PPACA) External Review Regulations

New Opportunities for Independent Review Organizations (IROs)

URAC IRO Accreditation

URAC is an independent, nonprofit organization well-known as a leader in promoting health care quality through its accreditation, education, and measurement programs. Since 1990 URAC has offered a wide range of quality benchmarking programs and services that keep pace with the rapid changes in the health care system, and provide a symbol of excellence for organizations to validate their commitment to quality and accountability. URAC’s IRO Accreditation product, first developed in 2000 and offered as External Review Organization Accreditation, is an example of such a program. Ever vigilant to keep pace with the changing health care landscape, URAC’s version 2.0 was a major revision to the product and also offered the opportunity to re-cast the product as Independent Review Organization (IRO) Accreditation. Through its broad-based governance structure and an inclusive standards development process, URAC ensures that all stakeholders are represented in establishing meaningful quality measures for the entire health care industry. Since then, our standards have been recognized as setting the benchmark for review organizations prompting the Federal recognition of URAC’s IRO accreditation in health care reform to assure all American consumers of due process in the event of denied insurance enrollment or denied claim of a health care services.

PPACA regulations create opportunities for Independent Review Organizations (IROs)

The Patient Protection and Affordable Care Act (PPACA), also referred to as the Affordable Care Act and its implementing regulations, creates new consumer protections, opportunities for IRO participation, and the requirement for accreditation. Under PPACA new standards are required for non-grandfathered plans and issuers regarding both internal claims and appeals and external review for plan years (in the individual market, policy years) beginning on or after September 23, 2010.1

Plans with consumers enrolled on March 23, 2010 are grandfathered and exempt from these new rules. It is expected that the number of grandfathered plans will decrease over time. In the individual market, frequent enrollee terminations will result in lower enrollment in grandfathered plans and more enrollees in plans subject to the new appeals and external review requirements. Further, grandfathered plans are limited in the types of changes they make in order to keep their grandfathered status. For example, a reduction in benefits may be significant enough to cause a plan to relinquish its status. A previously issued Interim Final Rule provides comprehensive guidance on the types of changes to a grandfathered plan that will cause a loss of grandfathered status.2 Additionally, because they want to provide enrollees greater consumer protections or do not want to comply with the administrative requirements grandfathered plans are subject to, grandfathered plans may also decide to voluntarily relinquish their grandfather status.

Under the Affordable Care Act, plans and issuers must arrange for external reviews that comply with either an approved State external review process or the Federal external review process. A State external review process will apply only if the State adopts and incorporates the minimum consumer protections under the NAIC Uniform Health Carrier External Review Model Act (NAIC UER Act). Wide variation exists in the way States provide oversight of external reviews. While only a few States have adopted the entire NAIC UER Act standards, most States have some kind of external review laws in place, which may include portions of the NAIC UER Act. Implementation of the Interim Final Rule issued July 23, 2010 (the IFR) creates a transition period until July 1, 2011 for States to
implement minimum NAIC UER Act standards, which will likely result in more uniform application of NAIC UER Act standards.\(^3\)

Important to IROs is that State external review processes require IROs conducting external reviews of internal appeals to be accredited by URAC (or other nationally recognized accrediting entity). States are required to maintain a list of accredited IROs from which they select an IRO to conduct an external review.

For plans not subject to a State external review process a Federal external review process will apply. The Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) will be issuing specific guidance on the Federal external review process, but the IFR and technical guidance for self-insured plans indicate that the Federal external review process will also include the minimum NAIC UER Act standards and the requirement that IROs be accredited by a nationally recognized accrediting organization.

URAC’s IRO accreditation standards incorporates NAIC UER Act standards and ensure that an organization meets minimum regulatory requirements at all times through an ongoing comprehensive mechanism to identify and address new State or Federal requirements. Additionally, the URAC accreditation process enables IROs to implement sound business practices for continuously improving quality initiatives, application of appropriate clinical guidelines, and mechanisms for ongoing assessment of an IRO’s own policies and procedures. IROs and other quality improvement organizations and managed care organizations can participate in State external review or Federal external review processes through accreditation.

The URAC standards promote the utilization of the most appropriate clinical expertise for each specific external review case. This protects the consumer by determining when denied services are medically necessary or beneficial. Proper reviews can also lead to health care cost savings by identifying instances where health care services are either experimental or not medically necessary and therefore should not be covered under a plan’s benefit package.

### IRO procedures to receive and complete external reviews from group and self-insured plans

Accredited IROs will typically receive claims for external review after internal appeals are exhausted. Group health plans will often have two (2) levels of internal appeals before a claim is eligible for external review, while individual insurers only have one (1) level. Certain circumstances may make an adverse benefit determination immediately eligible for external review such as a failure of the plan to adhere to all of the internal review requirements, a claim involving urgent care situations, or a claim involving an ongoing course of treatment.

IROs need to have specific policies and procedures for receiving and completing standard and expedited external reviews requested by plan enrollees and to continuously monitor the case review process to ensure the timeframes and independent peer reviewer requirements are indeed met for each and every case. As mentioned earlier, unlike group health plans, self-insured plans must comply with the Federal review process. These rules describe procedures for how self-insured plans request external reviews and how IROs will conduct standard and expedited reviews. Like the State external review process, the Federal review process for self-insured plans is likely to require that IROs conducting reviews be accredited by URAC (or another nationally recognized accrediting organization).

For standard reviews, plan enrollees may request an external review of an adverse benefit determination within four (4) months of notice of such determination. Upon receipt of a request for external review, the plan will then have five (5) business days to complete a preliminary review to determine if the claim is eligible for external review. The preliminary review examines whether the claimant was covered under the plan at the time the service was provided and that the internal appeals process has been exhausted. After one (1) business day, the commissioner will randomly assign one of the State’s contracted IROs to complete the review. The IRO will conduct its own preliminary review to determine whether the case relates to medical necessity and appropriateness or an administrative issue, or both. An IRO has 45 days from receipt of the request to complete an external review.

Expedit ed reviews are required when an adverse benefit determination, if not handled in an expedited manner, will seriously jeopardize the life or health of the claimant. In these cases, a preliminary review by the plan is completed immediately upon request for expedited review. Once the selected IRO receives case information from the health
carrier or its designee utilization review organization, it must render and communicate an external review decision within 72 hours (if the initial notice was not in writing, then the IRO must provide its decision in writing within 48 hours of the first notice.)

**Minimum qualification for reviewers with accredited IROs**

URAC accreditation ensures that IROs are utilizing the most appropriate clinical and administrative procedures. For each individual case, reviewers with specialized expertise are selected as warranted for the particular medical issue and type of medical service under review.

To be accredited, IROs must demonstrate that peer reviewers are credentialed and have the appropriate professional qualifications necessary for proper consideration of external review cases. At a minimum, procedures are in place to verify that reviewers maintain the applicable licensure and board certifications. Credentialing also includes a review of any history of sanctions or disciplinary actions and the presence of any potential conflicts of interest. Ongoing review of these credentialing criteria allows the IRO to maintain a panel of reviewers with varying expertise for assignment to various cases.

When assigning a reviewer or multiple reviewers to a given case, IROs should have established criteria for determining the specific expertise necessary, which will vary by case. Specifically, when there is a need for multiple disciplines for a given case, the reviewer(s) will possess the applicable board certification and licensure, and the scope of licensure and professional experience encompasses the health service, treatment, or issue under review.

Administrative external review processes may involve an interpretation of a health benefits plan contract or applicable State and Federal law. IRO procedures should outline if the administrative issue requires a legal review and if a clinical reviewer should also participate in the review.

**Situation impacting the decision to conduct an external review**

**Conflict of interest**

Prior to contracting, an IRO attests to any potential conflicts of interest that it may have. In addition, once an IRO receives a request for external review, it may conduct a preliminary review to rule out any conflict of interest that might exist with regards to a specific case. This would exist, for example, if the IRO was involved with the initial appeal. Preventing conflicts of interest is a fundamental concept of conducting appropriate case review and IROs must implement procedures to screen and prevent conflicts when assigning reviewers to a case. In turn, the reviewer accepting the case must sign a conflict of interest attestation.

There are some situations when, even with a conflict of interest, an IRO may proceed with an external review. For example, if the case involves a rare or novel medical issue and requires unique expertise, an IRO may proceed with the review if all affected parties provide written consent.

**Medical necessity and appropriateness case processing**

When processing a case regarding medical necessity and appropriateness, an IRO and its reviewer must consider all pertinent information when making a determination. This includes the consumer’s medical records and the attending provider’s recommendation. The review of this documentation should also take into account current research of evidence-based practice guidelines and nationally accepted clinical standards. IROs may consider the particular health plan’s criteria of what constitutes medical necessity.

**Experimental/investigational case processing**

For cases addressing whether a treatment is experimental or investigational in nature, the IRO must consider all information required for medical necessity. In addition, examination of existing medical research and peer-reviewed literature is required to determine whether the treatment at issue will result in a desired clinical outcome, while accounting for patient safety. IROs should also seek guidance from other decision-making models based on clinical trials and clinical research, as well as expert opinion. Like the reviews for medical necessity, IROs should consider the particular health plan criteria for experimental and investigational treatments.

**URAC IRO Accreditation - providing you the tools to meet PPACA requirements**

IROs have an opportunity through URAC accreditation to be an active participant in the new external review processes under the new PPACA regulations. The expected decline in grandfathered plans, coupled with the Federal review process (applicable to self-insured and other plans not covered by State review processes) requiring IRO accreditation, plus the estimated 32 million Americans who will now receive coverage under health care reform, may lead to increased opportunity for IROs to conduct external reviews.

URAC accreditation is a continual process of review, inspection, and attestation. Beginning with the initial desk top review where policies and procedures are checked and reviewed to
our comprehensive on-site and annual compliance monitoring inspections, URAC IRO Accreditation ensures that organizations implement and maintain policies and procedures for sound business practices, quality and performance improvement, and for conducting standard and expedited reviews within required time frames free from conflict. Accreditation offers industry best practices and promotes the utilization of the most appropriate clinical expertise and accepted principles for medical necessity and appropriateness. At any time a consumer, insurance issuer, or provider may submit a complaint about an accredited company via URAC’s website.

**URAC’s Uniform External Review (UER) Accreditation ensures compliance with Case Referral Procedures**

To fully consider the impact of the Affordable Care Act, one must also consider the new rules imposed on new group health and self-insured plans as well. The IFR states that group health plans and issuers must comply with the new external review processes. In States that have implemented an external review process, plans must comply if the State’s external review process applies to and is binding on an issuer of health insurance coverage. Moreover, that process must at least include the protections in the NAIC UER Act standards. Self-insured plans that are not covered by State insurance regulation, and self-insured or fully-insured plans that do not have to abide by a State external review process, must comply with a Federal external review process that is consistent with the NAIC UER Act. Under the IFR, for plan years (in the individual market, policy years) beginning on or after September 23, 2010 health plans and issuers must have an internal appeals process that:

- Allows consumers to appeal when a health plan denies a claim for a covered service or rescinds coverage;
- Gives consumers detailed information about the grounds for the denial of claims or coverage;
- Requires plans to notify consumers about their rights to appeal and instructs them on how to begin the appeals process;
- Ensures a full and fair review of the denial; and
- Provides consumers with an expedited appeals process in urgent cases.

The IFR also requires, by July 1, 2011, that:

- All consumers in health plans have access to internal and external appeals processes that are clearly defined, impartial and designed to ensure access to health care when it is needed and appropriate;
- Internal and external appeal processes will be standardized;
- A review by independent body be assigned by the state.
- States are encouraged to make changes in their external appeals laws to adopt these standards before July 1, 2011. If States don’t meet these standards, consumers will be protected by comparable Federal External appeals standards.

URAC’s UER Accreditation demonstrates compliance with the appeal process required under health care reform, which applies to ERISA plans as well. URAC’s UER Standards are modeled after the NAIC Model Act and as a result, UER Accreditation streamlines the process for ERISA plans to comply with federal health reform.

**Endnotes**

1. Patient Protection and Affordable Care Act § 10101(g).
2. Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 34,538 (June 17, 2010).