BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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December 8, 2010

Elizabeth Fowler
Director of Policy, Office of Consumer Information and Oversight
Department of Health and Human Services

The Honorable Phyllis C. Borzi
Assistant Secretary, Employee Benefits Security Administration
Department of Labor

Submitted via the Federal Rulemaking Portal: http://www.regulations.gov

Re: Federal External Review Process; Request for Information (OCIIO–9986–NC)

Dear Director Fowler and Secretary Borzi:

The Blue Cross and Blue Shield Association ("BCBSA") – a national federation of 39 independent, community-based and locally operated Blue Cross and Blue Shield companies that collectively provide health coverage for nearly 98 million members – appreciates the opportunity to submit comments on the **Federal External Review Process; Request for Information** as issued in the *Federal Register* on November 17, 2010 (75 Fed. Reg. 70160).

This letter provides answers to selected questions posed in the RFI about a Federal external review process. However, we believe the Departments should consider the RFI questions against the broader question of how State and Federal external review processes are intended to align. Before addressing specific questions, we respectfully request that the Departments provide additional clarity around the extent of alignment.

I. Aligning State and Federal External Review Processes

The RFI requests comments on operational issues associated with implementation of a Federal external review process for health coverage in States that do not have an applicable external review process that meets the minimum Federal standards. A State would have an applicable external review process if it makes the

necessary changes in an existing external review law to incorporate additional consumer protections. Since the Interim Final Rules (the "Rule") for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act (ACA) directs that State external review processes include, at a minimum, the consumer protections of the NAIC Uniform Model Act, a State might reasonably conclude that its external review law is applicable if the law is based on the NAIC Uniform Model Act.

However, in two important ways – concerning the scope of appeals and the timing of payments – the NAIC Model Act and the Rule are not in alignment, creating ambiguity for States.

Scope. The Rule states that external review shall apply to "adverse benefit determinations. . . that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness *of a covered benefit* [emphasis added]." The term "effectiveness of a covered benefit" does not appear in the NAIC Model Act. Under the NAIC Model Act, health plan members may appeal denials based on medical necessity, appropriateness, health care setting, level of care, or *effectiveness of the health care service* or treatment [emphasis added]. We understand that some Department officials have remarked that minimum State external review requirements are not intended to be different from the NAIC Model Act. If so, then it would be helpful to have formal sub-regulatory guidance that the term "effectiveness of a covered benefit" is meant to have the same meaning as "effectiveness of the health care service or treatment." Otherwise, States that believe their laws incorporate the minimum consumer protections, because their laws follow the NAIC Model Act, may find that their laws are not applicable and the Federal external review process will apply.

The scope of the Federal review process itself is another area where the NAIC Model Act and the Federal requirements do not align. Although the ACA directs the Secretary to develop "an effective external review process that meets minimum standards" similar to the NAIC Model Act, the Rule allows federal reviews for any adverse benefit determination (except eligibility denials), which includes claims determinations and denials based on benefit and coverage determinations (e.g., the deductible amount applied by the plan) where the member is paid at less than 100% of what was claimed and the member bears liability. Thus, two people covered by state-regulated insurance could face different external review options depending on whether their State had or did not have an applicable external review process. This does not seem to be consistent with the guidance that authorizes the Departments to establish a Federal external review process that is similar to a State external review process.

Payments. Technical Release 2010-01 requires that upon receiving a notice of a final external review decision reversing a plan's adverse benefit determination, the plan immediately must approve the coverage and pay benefits for the claim. This

departs from the NAIC Model Act, which requires only that the health insurer immediately approve the coverage that was the subject of the adverse determination. Again, it would be helpful to have a clarification that if a State law follows the NAIC Model Act in requiring immediate approval of coverage, but not necessarily of payment, that the State would be considered to have an applicable external review process.

Therefore, we respectfully request that the Departments (1) Clarify that the scope of what is appealable in a State external review law is the same as in the NAIC Model Act; (2) Clarify that the payment requirement for a State external review law is the same as in the NAIC Model Act; and (3) Bring the scope of what is appealable in the Federal external review process into alignment with the scope required of State external review laws.

We appreciate your consideration of our requests. What follows are answers to selected RFI questions.

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II. Answers to Selected Questions in the Request for Information

1. What accreditation standards currently apply to IROs?

The primary accreditor of IROs is the Utilization Review Accreditation Commission (URAC). If the Departments enter into contractual relationships with one or more IROs, we recommend that URAC accreditation be a contractual requirement. If not, conflicts may arise with requirements in health plans' other contracts (e.g., with the Office of Personnel Management or with many large, private employers) for URAC accreditation.

2. *What credentialing standards do IROs require for medical and legal reviewers? Is credentialing required or voluntary?*

Typically, the professionals who conduct medical review must have a valid state license, not have any criminal violations, and be board certified in the respective specialty or sub-specialty.

As most IROs do not conduct reviews of coverage issues, the credentialing standards for legal reviewers have not yet been defined. However, legal reviewers do not necessarily need to be attorneys. A paralegal, a registered nurse with a payer background, are two examples of the sorts of professionals who could handle a simple review. To keep down the costs of review, we recommend reserving use of attorneys for complex non-clinical reviews. When used, attorneys should be licensed in good standing with their respective bars and experienced in health insurance coverage issues.

3. What procedures are currently used by IROs to assure that reviewers do not have conflicts of interest with disputing parties?

Most IROs have a conflict of interest statement at the end of the consult that the reviewer must sign.

4. What are IROs' current capacity for performing reviews? Does staffing and the time necessary for performing a review differ based on the type of claim (e.g., medical necessity, experimental/ investigational treatment, coverage issues, etc.)?

A good rule of thumb is the greater the number of pages in the medical record, the more expensive the review. In general, clinical cases take longer to review than cases involving reimbursement; experimental/investigational cases are often more expensive than medical necessity cases (in a number of states, reviews to determine medical necessity require only one reviewer but reviews of experimental services require a panel of three reviewers); and expediting a review of any sort raises costs considerably. To provide some context, the State of Ohio reports that over a two-year period (2003-2004) the cost for a standard 30-day review of medical necessity and experimental/investigational denials averaged $580; the cost for an expedited seven-day review averaged $1,800.

Some reviews need board-certified sub-specialists. This can create time delays because finding sub-specialists who have time available and who have not previously been involved in the same case can be difficult. Areas of particular concern are pediatric subspecialties and sub-subspecialties in oncology (e.g., therapeutic radiation oncology). For example, the American Academy of Pediatrics lists only 362 physicians nationwide as members who are board certified in pediatric hematology-oncology.

8. What is a reasonable amount of time for a contractor to become fully operational (have all systems in place to conduct external reviews) after the date of a contract award?

No amount of time is reasonable: it is not our practice and we do not recommend contracting with anyone who cannot perform the external review function on the date the contract becomes effective.

10. Do IROs currently operate nationally or in limited geographic areas? Would IROs that currently serve local areas be able to expand their service areas to possibly include other geographic areas such as other States? Are there any State and/or local licensing requirements?

44 States and DC require that IROs seek licensure or certification. However, State requirements may not be relevant because any requirement applicable to the Federal external review process is likely to supersede State laws. The same reasoning would apply to common requirements that medical professionals be

licensed in the State of the plan that is licensed as a health insurer. There is no compelling public policy reason that the license of the reviewer be issued by the State of the health insurer – what matters is that the medical professional is licensed in good standing.

11. Are there any special considerations HHS and/or DOL should be aware of in considering a specialized contract for urgent care appeals or for experimental and investigational treatments? Would such an approach have an impact on coordination?

The scarcity of certain sub-specialists discussed in question 4 may pose problems for experimental or investigational treatments, which disproportionately include oncology care.

12. Please describe the difference in standard operating procedures and resources (time, cost, personnel) for appeals that involve only medical necessity and those that involve both medical necessity and coverage questions.

In reviewing clinical cases, the plan's medical policies and other relevant information to include peer review consults must be obtained as well as the documentation submitted with the appeal. All of this information must then be reviewed against the member's policy.

In reviewing coverage determinations, one only reviews the member's policy and claim processing information.

16. What specific requirements should be applied to IROs to evaluate progress toward performance goals? What performance goals are the most appropriate?

Many States audit most or all IRO decisions for compliance with requirements regarding the time frame for issuing a decision and for the content of written notice of determinations. The Departments should implement a similar audit policy, and also require that IROs demonstrate the average completion time for appeals from the previous year, including the number of appeals received, types, and turn-over rates.

As part of the audit process, we recommend that the Departments focus also on the *validity* of IRO decisions – that is, are they based on the best available medical evidence – and on the decisions' *reliability*.

For validity, we recommend that the Departments require IROs to consider "the most" appropriate practice guidelines. The term "the most" appears in the NAIC Model Act, but was dropped from Technical Release 2010-01, which refers simply to "appropriate practice guidelines." Eliminating "the most" could be construed as lowering the burden of proof for the reviewer's rationale for the reviewer's decision,

as it is easier to claim that one's decision is based on appropriate guidelines than to claim that one's decision is based on the most appropriate guidelines.

For reliability, we recommend that the Departments monitor and analyze (1) inter-rater reliability; (2) individual rater reliability; and (3) inter-IRO reliability. Inter-rater reliability usually refers to the degree of consensus between two or more coders or raters in the same IRO: plans often have a contractual requirement that IROs reach a certain acceptable level of inter-rater reliability. IROs should be required to explain how they conduct peer review to ensure high inter-rater reliability on clinical and non-clinical decisions.

It is equally important that an individual reviewer not be prone to wide variations on similar cases. For example, if an individual reviewer's determination of cases with similar fact patterns varies widely over time, then that reviewer should be called on to justify his or her decisions. And in a national program where only a handful of IROs enters into a contractual relationship to conduct external reviews, the degree of consensus between two or more IROs is especially important. If one IRO consistently upholds certain determinations and another IRO consistently reverses them, someone is not considering the most appropriate medical evidence.

Finally, we recommend that in determining whether an item or service should be covered, the reviewers follow the definitions in the health plan contract. If each reviewer is permitted, for example, to apply his or her own criteria as to what constitutes experimental/investigational, then inter-rater and inter-IRO reliability will suffer.

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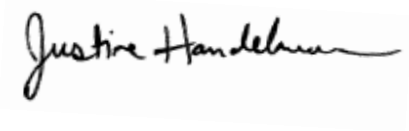
We appreciate your consideration of our responses to the RFI and thank you for considering our suggested recommendations and request for clarifications. If you have any questions, please contact Joel Slackman at 202.626.8614 or Joel.Slackman@bcbsa.com.

Sincerely,



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