

Legal News Alert is part of our ongoing commitment to providing up-to-the minute information about pressing concerns or industry issues affecting our health care clients and colleagues.

If you have any questions about this alert or would like to discuss this topic further, please contact your Foley attorney or any of the following individuals:

Jeffrey R. Bates
Los Angeles, California
213.972.4682
jbates@foley.com

Lena Robins
Washington, D.C.
202.295.4790
lrobins@foley.com

Chris E. Rossman
Detroit, Michigan
313.234.7112
crossman@foley.com

Lawrence W. Vernaglia
Boston, Massachusetts
617.342.4079
vernaglia@foley.com

Medicare Part A Proposed Appeal Rules May Be Finalized in Near Future

After several years of deliberation, the Centers for Medicare & Medicaid Services (CMS) likely will finalize new and restrictive Medicare Part A appeal requirements in the near future. These rules will limit dramatically the historical practices of hospitals and other providers challenging cost report-based intermediary determinations found in the Medicare Notice of Program Reimbursement (NPR). Providers will need to implement new and different management approaches in order to rapidly respond to NPRs once these rules are in effect.

Background

On June 25, 2004, the CMS issued proposed rules that would update, clarify, and revise various provisions of the regulations governing the Medicare Part A provider appeal process (Proposed Rules). Normally, the CMS is required to publish final rules within three years after publication of proposed rules. However, the CMS stated that it was unable to meet the three-year deadline due to the complexity of the policy and legal issues raised in the public comments that it received, and it extended the deadline for publication of the final rule for an additional year, until June 25, 2008. The Proposed Rules are currently before the Office of Management and Budget (OMB) for its review, which is typically the last step before proposed rules are issued as final rules. Depending on the OMB's action, the Proposed Rules may be issued in final form in the near future.

The Proposed Rules would make a number of significant changes to the appeal process before the Provider Reimbursement Review Board (PRRB). Most of the regulations governing the appeal process at the PRRB are approximately 30 years old. The CMS stated that it expected that revisions to the appeal regulations would lead to a more effective and efficient appeal process, and would help the PRRB reduce its backlog of approximately 10,000 cases.

What follows are some of the most significant changes in the Proposed Rules.

Limitation on the Addition of Issues to the Appeal

The most controversial aspect of the Proposed Rules is the proposal to limit the right of providers to add issues to an existing PRRB appeal. Under current regulations, a provider may add a specific matter to the original hearing request at any time before the commencement of the hearing. This permits providers to add issues that come to light based on further review of the cost report or the fiscal intermediary's audit report. Under the current rules, providers are not required to explain why they did not include the issue in the original hearing request, and there is no penalty for adding issues after the hearing request has been submitted.

Often providers do not learn about important legal and reimbursement developments until years after the issuance of the NPR. The current rules allow providers to incorporate those developments into their PRRB appeals as they learn of favorable decisions by the PRRB or the courts in other cases. Furthermore, at the time an appeal is filed, providers may not possess all of the facts or documentation with which to determine whether a particular issue should be appealed. Indeed, some providers may avoid appealing certain issues because they are not certain that an appeal would be meritorious, but may do so once further research or factual development confirms that an issue is suitable for appeal.

Under the Proposed Rules, providers would be allowed to add issues to their original hearing request only within 60 days after the expiration of the time limit for making the original appeal request. As under current regulations, providers would have 180 days from the date on which the fiscal intermediary issues its NPR to file their appeals. Thus, providers would be barred from adding issues to an appeal later than **240 days** after issuance of the NPR. There are no exceptions to this time limit, whether for good cause or for any other reason.

As justification for this proposal, the CMS states that permitting the addition of issues at any time before the hearing is untenable, and that the availability of a long period for adding issues has become a major obstacle to the PRRB's efforts to reduce its case backlog.

In fact, however, there are many reasons for the PRRB's backlog, and it is questionable whether the addition of issues to existing appeals is a significant factor contributing to the backlog. Furthermore, in light of the fact that appeals are not scheduled for hearing for at least several years after the appeal is filed, there is little justification for the proposed 60-day time limit for adding issues. Indeed, the current rules use the hearing date (which is set by the PRRB, and not by the provider or the intermediary) as the deadline for adding issues.

If the proposed time limit on adding issues to an appeal is adopted, providers will be required to conduct a comprehensive review of the cost report and the NPR in order to identify all of the issues that should be appealed. The Proposed Rules likely would result in providers appealing more issues in their hearing requests as "protective filings" or place-holders. If the provider is unable, at the time of filing an appeal, to make a final decision as to whether an issue should be appealed, it likely will include the issue in the hearing request in order to preserve its appeal rights. Thus, it is questionable whether the proposed time limit on adding issues will have the desired effect of expediting the PRRB appeal process.

The CMS did not explain in the Proposed Rules how the rules would apply to existing appeals, and it is unclear how they would apply retroactively to existing appeals. The CMS also might include a provision limiting the time period for providers with existing appeals to add issues to their appeals. While there would be grounds to challenge such an application on due process grounds or as retroactive rulemaking, providers should be aware that this is a possibility.

In light of the possibility that the right to add issues may be restricted if and when the Proposed Rules are finalized, providers should evaluate whether there are additional issues that should be

added to their existing appeals, and should include all likely appeal issues in future hearing requests.

Failure to Follow PRRB Rules

The CMS proposes to add a new regulation that would specify that the PRRB has authority to take appropriate actions for failure to follow established procedural requirements or for inappropriate conduct during hearings. If the provider fails to meet any filing or procedural deadlines or other requirements established by the PRRB, the PRRB could dismiss the appeal, issue an order requiring the provider to show cause why the PRRB should not dismiss the appeal, or take other appropriate action.

If the intermediary fails to meet any filing or procedural requirements set by the PRRB, the PRRB could issue a decision based on the written record submitted up to that point or take other appropriate action. The express statement that the PRRB may issue a decision even though the intermediary has not filed a position paper or taken other action is an important reminder. Currently, intermediaries that delay filing position papers in PRRB cases suffer little consequence, other than formal reprimands from the PRRB to the CMS. If the PRRB would rule regularly in favor of providers' substantive positions when the intermediaries fail to participate actively in the appeal process, it would do much to facilitate the prompt resolution of appeals.

Reopening Procedures

The Proposed Rules would provide that a change of legal interpretation or policy by the CMS in a regulation, CMS ruling, or CMS general instruction is not a basis for reopening a CMS, PRRB, or intermediary decision. Thus, reopenings would not be permitted based on a change in legal interpretation or policy. Prior court rulings have made it clear that providers have no right to appeal a refusal to reopen. This restriction on reopenings is a significant statement to providers that underscores the importance of filing appeals to protect their rights through the formal appeal process, and not to rely on the possibility that an intermediary might agree to reopen a prior determination.

PRRB Draft Instructions

Subsequent to publication of the Proposed Rules, the PRRB in February 2005 issued Draft Instructions that would further restrict the procedures for PRRB appeals. These Draft Instructions were not promulgated in accordance with the notice and comment provisions of the Administrative Procedure Act and are separate from the Proposed Rules. There are a number of areas in which the Draft Instructions overlap or are inconsistent with provisions of the Proposed Rules. The PRRB has indicated that it will not finalize the provisions of the Draft Instructions until the Proposed Rules are finalized.

The most significant and controversial aspect of the Draft Instructions concerns the appeal information and documentation that must be submitted with the provider's hearing request. **Under the Draft Instructions, providers in their initial hearing request would be required to provide the explanation and documentation that currently is required in the provider's preliminary position paper.** In the hearing request, the provider would be required to state, in numbered paragraphs, the material facts supporting the provider's claim. If any documents necessary to support the appeal were not furnished previously to the intermediary, the provider would be required to send those documents to the intermediary with the hearing request. The provider would have to describe any legal issues in dispute and the authorities upon which it relies. This would constitute a major change to the current notice filing for appeals, and would greatly increase the burden on the provider in the early stages of the appeal.

Action Steps for Providers

As noted above, neither the Proposed Rules nor the Draft Instructions are currently in effect. Given that the Proposed Rules are now at the OMB for review, it is likely that the Proposed Rules (or some variation on the Proposed Rules) could be issued as Final Rules in the near future, which could be as early as spring 2008. It is unknown whether or when the Draft Instructions might be finalized. In light of the impending rule

ABOUT FOLEY

Foley & Lardner LLP is a national law firm providing comprehensive legal services for innovative enterprises in the health care, pharmaceutical, biotechnology, and biomedical sectors. Our Health Care attorneys provide counsel on financial transactions, mergers, acquisitions, affiliations, joint ventures, regulatory and government compliance, and business operations. With offices throughout the United States and the backing of Foley's Health Care Industry Team — consistently ranked as one of the top health care law firms nationally and regionally by *Chambers USA* — Foley is well-positioned to serve the wide-ranging needs of health care entities across the country.

Foley.com

Foley & Lardner LLP Legal News Alert is intended to provide information (not advice) about important new legislation or legal developments. The great number of legal developments does not permit the issuing of an update for each one, nor does it allow the issuing of a follow-up on all subsequent developments.

If you do not want to receive further Legal News Alert bulletins, please e-mail info@foley.com or contact Marketing at Foley & Lardner LLP, 321 N. Clark Street, Suite 2800, Chicago, IL 60610 or 312.832.4500.

changes, it is advisable that providers take steps now to prepare for significant restrictions in their abilities to challenge NPR determinations in the event that the Proposed Rules or Draft Instructions are issued in final form. Among these steps are:

- Assessment of existing appeals already filed with the PRRB, with the goal of determining whether there are additional issues that need to be included in the appeal, and what information or research is necessary to make a decision regarding those issues. If the restriction on adding issues in the Proposed Rule is retroactively applied to existing appeals, providers will need to be prepared to include additional issues in their appeals within a short time.
- Evaluation of providers' internal processes and resources for prompt review and analysis of NPRs. If the Draft Instructions are finalized, providers will need to file a thorough appeal brief within 180 days of the issuance of the NPR. Providers should assess whether additional internal or external resources will be needed to accomplish this.