HEALTH CARE
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CMS Issues Proposed Overpayment Refund Regulations for the 60-Day Rule

On February 13, 2012, CMS issued long-awaited guidance under the "60-Day Rule" (Proposed Rule). The 60-Day Rule, enacted under the 2010 health reform law — the Patient Protection and Affordable Care Act (PPACA) Section 6402(a), codified at Section 1128J(d) of the Social Security Act — requires all Medicare or Medicaid participating providers and suppliers to report and refund known overpayments by the later of 60 days from the date the overpayment is "identified" or the date the corresponding cost report is due.

The 60-Day Rule has caused considerable scrambling by providers, suppliers, and affected health plans seeking to meet this very short window — but lacks regulatory guidance as to a number of critical definitions, including when an overpayment is actually "identified" and when the 60-day clock starts to tick. Yet, the 60-Day Rule is a statutory requirement in effect since March 23, 2010, and a provider that fails to meet this short deadline can suffer a variety of hardships, including damages and penalties under the False Claims Act and civil monetary penalties up to and including exclusion from participation in federal health care programs. The Proposed Rule is intended to establish the rules and regulations under the 60-Day Rule and answer some of these important questions.

In many respects, the Proposed Rule parallels the statutory language of the 60-Day Rule, but CMS introduced two important changes: 1) a "reasonable inquiry" principle, offering greater flexibility for when the 60-day clock starts running; and (2) a proposed 10-year look-back period for retrospective overpayment reviews that significantly expands the potential liability of providers when refunding overpayments.

Reasonable Inquiry

Under the Proposed Rule, an overpayment is "identified" when a person has "actual knowledge of the existence of an overpayment, or acts in reckless disregard or deliberate ignorance of the overpayment." Responding to concerns expressed by many in the provider community and health care bar, CMS acknowledged that the 60-day clock does not start running (i.e., an overpayment is not "identified") until ***after*** the provider has an opportunity to undertake a "reasonable inquiry" into the basis of the alleged overpayment.

CMS did not detail exactly what constitutes a "reasonable inquiry," but clearly will allow some flexibility in light of the different levels of review needed to address the wide variety of potential overpayments — ranging from simple claims issues to complex regulatory analyses. CMS did not propose that the 60-day clock start running on the first mere allegation or suspicion of an overpayment. Rather, CMS appeared to recognize that many sophisticated reimbursement questions require significant use of internal and external resources, due diligence, document review, and, occasionally, financial and statistical analyses. These important steps often cannot be completed within 60 days of the initial allegation of the overpayment.

Although the reasonable inquiry provision affords providers greater flexibility regarding the timing of refunds, CMS balanced it against the concept that providers or suppliers have a duty to promptly conduct this reasonable inquiry upon receipt of information that a potential overpayment has occurred. If the provider fails to make any reasonable inquiry, it may be found to have acted in reckless disregard or deliberate ignorance of the overpayment. According to CMS, defining "identification" in this way gives providers and suppliers an incentive to exercise reasonable diligence to determine whether an overpayment exists. Without such a definition, CMS believes some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research.

CMS also stated that "[w]hen a government agency informs a provider or supplier of a potential overpayment, the provider or supplier has an obligation to accept the finding or make a reasonable inquiry." At this point, the legal authority for this obligation seems unclear, as does what sort of government agency notice would trigger this obligation (e.g., remittance advice, general provider alert, RAC audits, informal letter to specific provider, preliminary audit report, or formal letter).

10-Year Look-Back Period

The most dramatic change proposed by CMS is an expansion of the look-back period for overpayments to 10 years. CMS chose this period to parallel the outside statute of limitations under the False Claims Act. But current Medicare reopening regulations permit look-back periods of only three or four years for simple overpayments (i.e., when there is no fraud, provider integrity issue, or similar fault). The Proposed Rule requires providers to report and refund overpayments received during the ***prior 10 years***. This represents a significant

change to current overpayment and refund practices. Should the Proposed Rule go into effect as drafted, this change would result in materially increased liability for providers and suppliers.

Other Important Points in the Proposed Rule

Several other important points should be noted by those trying to create or implement an overpayment refund policy.

- Under the Proposed Rule, the existing voluntary refund process in Chapter 4 of the Medicare Financial Management Manual will be renamed the "self-reported overpayment refund process." This is the process providers and suppliers will use to effectuate refunds. Self-reporting should be made in accordance with the protocols of the local fiscal intermediary, carrier, or contractor. CMS contemplates a standardized form to be used for repayments, but does not have one yet.
- The Proposed Rule reflects the existing statutory duty to report and refund overpayments within 60 days. That duty is ***not*** deferred until the regulations are finalized. Providers and suppliers currently face False Claims Act risk and other penalties if they fail to promptly report and refund known overpayments.
- The Proposed Rule only applies to traditional Medicare Parts A and B, even though the PPACA also includes Medicaid, managed care organizations, Medicare Advantage, and Part D programs. The statutory 60-Day Rule with respect to those programs continues, even without regulatory guidance.
- If an overpayment is claims-related, and would not be impacted by reconciliation of the cost report, the refund should not be delayed until reconciliation of a cost report. For example, issues involving upcoding must be reported and returned within 60 days of identification because the upcoded claims for payment are not submitted to Medicare as "costs" in the form of cost reports.
- The CMS Stark Self-Referral Disclosure Protocol (SRDP) tolls the obligation to refund the overpayment, but does not toll the obligation to report it. The OIG Self-Disclosure Protocol (SDP) also tolls the refund obligation, and a timely report to OIG under the SDP satisfies the reporting requirements under the 60-Day Rule.

Recommendations and Implications

In light of the ambitious changes in the Proposed Rule, particularly the significant expansion of potential liability associated with a 10-year look-back period, health care suppliers and providers need to understand the consequences of the 60-Day Rule and consider what they could do proactively to meet the requirements.

- Consider creating and implementing an appropriate policy and procedure for reporting and refunding identified overpayments. Keep in mind, providers and suppliers must currently meet the 60-day requirements already in place by virtue of the PPACA, even though the Proposed Rule is not finalized. For more information on how to create such a policy, please see our prior coverage of the 60-Day Rule at http://tinyurl.com/7qa2nvp.
- Health care entities and other affected parties should consider submitting comments to the Proposed Rule so CMS fully understands and appreciates the impact the Proposed Rule will have on providers' and suppliers' operations. Comments to the Proposed Rule will be accepted for 60 days after the date of publication in the Federal Register, and concerns with the Proposed Rule can be addressed through the comment process. As important stakeholders in the health care industry, providers and suppliers will help CMS identify changes to improve and clarify the existing Proposed Rule. For businesses interested in this opportunity, health care counsel and public policy professionals can help prepare comments to ensure those concerns are articulated and fully considered by CMS.

The Proposed Rule is scheduled for official publication in the *Federal Register* Thursday, February 16, 2012. However, you can access an advance copy of the Proposed Rule at http://tinyurl.com/7m94yui.

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