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Proposed overpayment regulations issued for 60-day refund rule

» Overpayments must be returned within 60 days of when identified.
» "Identified" means actual knowledge or reckless disregard of the overpayment.
» Providers may conduct a "reasonable inquiry" before the clock starts.
» CMS proposes a 10-year look back period for overpayment reviews.
» Organizations must create a viable, flexible policy for overpayments.

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On February 13, 2012, CMS issued a set of proposed regulations under the 60-day refund rule (the proposed rule). CMS's proposed rule is responsive to industry concerns, but also opens up a significant amount of new liability. The 60-day refund rule, enacted under the Patient Protection and Affordable Care Act (PPACA) and codified at 42 U.S.C. section 1320a-7k(d), requires Medicare or Medicaid participating providers, suppliers, and plans 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 refund rule created significant burdens for providers, suppliers, and affected health plans attempting to meet this short window. Regulatory guidance is lacking for a number of definitions, including when an overpayment is actually "identified" and when the 60-day clock starts to run. The proposed rule attempts to answer some of these important questions. An analysis of the proposed rule offers providers and suppliers some interpretive guidance and a preview of what they can expect when the final regulations are issued.


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Background

Prior to the enactment of the 60-day refund rule, there was a long history of disagreement between the health care bar, regulators, prosecutors, and the industry regarding whether or not there was a duty to affirmatively disclose overpayments. Some providers argued there was no duty to refund innocent overpayments, but the government disagreed and made efforts to pursue *qui tam* cases and settlements on the reverse false claim theory (i.e., where an obligation to pay or transmit money to the government is fraudulently evaded).

Much of this debate was settled with the enactment of Section 1320a-7k(d) on March 23, 2010. Specific to overpayments, PPACA included the following three interrelated provisions:

- Providers have an obligation under the False Claims Act (FCA), including an express duty to refund and report Medicare and Medicaid overpayments by the later of 60 days after the overpayment is identified or the date the corresponding cost report is due. Failure to report and return the overpayment is an obligation for purposes of the FCA.
- Enhancements to the Civil Monetary Penalties (CMP) Law now provide CMPs for failing to report and return known overpayments within 60 days or when the cost report is due.
- Expanded exclusion authority under the Medicaid program for failure to report and return known overpayments.

Section 1320a-7k(d) itself states, in pertinent part, as follows:

(d) REPORTING AND RETURNING OF OVERPAYMENTS. —

(1) IN GENERAL. — If a person has received an overpayment, the person shall —

(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS. — An overpayment must be reported and returned under paragraph (1) by the later of —

(A) the date which is 60 days after the date on which the overpayment was identified; or

(B) the date any corresponding cost report is due, if applicable.

(3) ENFORCEMENT.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.

(4) DEFINITIONS. — In this subsection:

(A) KNOWING AND KNOWINGLY. — The terms 'knowing' and 'knowingly' have the meaning given those terms in section 3729(b) of title 31, United States Code.

(B) OVERPAYMENT. — The term "overpayment" means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

(C) PERSON. —

(i) IN GENERAL. — The term 'person' means a provider of services, supplier, Medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)).

(ii) EXCLUSION. — Such term does not include a beneficiary.

As can be seen from the statutory language, a number of important definitions are omitted and the statute leaves open the critical question of when the 60-day period commences. Prior to the issuance of the proposed rule, organizations were required to interpret and apply the statute as best they could within their existing compliance structure. This is because the 60-day refund rule is currently in effect and a provider that fails to meet the reporting deadline faces damages and penalties under the FCA, CMPs, and potential

exclusion from participation in federal health care programs.

Highlights of the CMS proposed rule

CMS's proposed rule explains when an overpayment is "identified" and how overpayments are to be reported and refunded. CMS's position on those two issues is largely consistent with the statutory language of Section 1320a-7k(d). CMS interpreted the statutory language in two important material ways:

- a "reasonable inquiry" principle offering a reasonable and measured approach to determining when the 60-day clock starts running; and
- a proposed 10-year look back period for retrospective overpayment reviews that significant expands the potential liability of providers when refunding overpayments.

The proposed rule only applies to traditional Medicare Parts A and B, even though Section 1320a-7k(d) also includes Medicaid, managed care organizations, Medicare Advantage and Part D programs. The statutory 60-day refund rule with respect to those programs remains in effect, even without regulatory guidance, although health plans and Medicaid providers likely will look to the proposed rule and any final regulations for guidance as to how to apply the statutory requirements.

When is an overpayment identified?

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. 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.

Reasonable inquiry

CMS did not detail what constitutes a "reasonable inquiry," but clearly CMS 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 the 60-day clock start running on the first mere allegation or suspicion of an overpayment. CMS appeared to recognize that many sophisticated reimbursement questions require significant use of internal and external resources, due diligence, and document review. These important steps often cannot be completed within 60 days of the initial allegation of the overpayment.

Although the reasonable inquiry rule affords 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 of a potential overpayment. If a provider fails to make any reasonable inquiry, it may be found to have acted in reckless disregard or deliberate ignorance of the overpayment. In many respects, this is consistent with the practices of providers with effective compliance plans even prior to the implementation of PPACA.

According to CMS, defining "identification" in this way gives providers and suppliers an incentive to exercise due diligence to determine whether an overpayment exists. Without such a principle, 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 when 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 such an obligation seems

unclear at best, as does what sort of government agency notice may 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 3 or 4 years for most situations (i.e., when there is no fraud, provider integrity issue, or similar fault). The proposed requirement to report and refund overpayments received during the prior 10 years 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.

Many providers and suppliers will find a 10-year look back period not viable, if only because that period extends beyond the current record retention rules and requirements under Medicare Conditions of Participation, Supplier Standards, and state laws on medical record retention (typically ranging from 5 to 7 years). The 10-year period represents a dramatic expansion of CMS's authority and reach into retrospective claims reviews.

Self-reporting process

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 has not yet created one.

If an overpayment is claims-related, and would not be impacted by reconciliation of the cost report, the refund should not be delayed (according to CMS) 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.

On a related note, CMS explained that 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 refund rule.

Drafting a policy and procedure on overpayments

Many organizations have already created policies and procedures on self-reporting of known overpayments. With the issuance of the proposed rule (and the eventual enactment of a final rule), those organizations will need to tweak their existing policies and procedures to conform to the new regulations. But for those organizations without any policy and procedure on overpayments, it is due time to start considering how to create such a policy (whether formally-promulgated or a well-designed guideline). Again, the proposed rule has not been finalized and it would be reasonable to commence work, but not publish a policy, until the regulations are final.

When drafting a policy on overpayments, it is important to acknowledge the legal requirements, but also properly balance competing duties, apply the law fairly, and mitigate risk. In connection with that, an organization should evaluate the following considerations:

- Develop a standard form to document an internal report of an alleged overpayment. Many of the elements on that form can

mirror the required elements of the official reporting form.
- Consider whether the overpayment investigation should be conducted under attorney-client and work product privileges. The organization should have a policy and procedure to assist in these determinations.
- Conduct and document employee interviews.
- Collect evidence and document the methodology used to determine if the alleged overpayment is a credible concern.
- Assess and analyze the causes of the overpayment as well as any defenses to the overpayment or limitations on the amount of overpayment calculated.
- Determine the amount of overpayment to report and return, and determine to whom the refund should be made. Document the methodology of how the refund amount was calculated.
- Determine what corrective action is necessary to address the root cause of the overpayment and prevent its future recurrence.

Consider those cases where the "reasonable inquiry" period is anticipated to continue for such a length of time that filing some preliminary "holding statement" with the Fiscal Intermediary/Carrier/MAC may be prudent.

When drafting an overpayments policy, the organization should also keep in mind the following considerations:

- Don't create a policy that requires an unworkable bureaucracy or over-complicated process. It should be nimble, clear, and easy to complete in a timely manner.
- Do create a policy that allows for flexibility when information changes/develops during the investigation.
- Do create a policy that demonstrates the effectiveness of the organization's compliance plan.
- Do include in the policy any necessary internal approvals which are required for processing of the refund, and build in time for securing these approvals.
- Don't create a policy that conflicts with the organization's internal accounting policies without first getting input from auditors and legal counsel.
- Do implement robust training and education around the policy, how to spot overpayments, the requirements for internal (or external) reporting, and the organization's commitment against retaliation for whistleblowers and reporters.

Conclusion

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 organizations need to understand the consequences of the 60-day refund rule and how to meet its requirements. A first step is to create and implement an appropriate policy and procedure for reporting and refunding identified overpayments. Organizations must currently meet the 60-day requirements already in place under Section 1320a-7k(d), even though the proposed rule is not finalized. Organizations that draw on the guidance in the proposed rule to create a viable policy for reporting and refunding overpayments should find themselves well-positioned when the final rule is issued.