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"60-Day Rule" Proposed Regulations Would Create Intense Time Pressure for Providers to Report and Return Overpayments

I. Introduction

On February 16, 2012, CMS published in the Federal Register its much-anticipated (and long-awaited) notice of proposed rule making (NPRM) regarding Medicare provider and supplier[1] obligations to report and return overpayments (Proposed Rule).[2] The Proposed Rule would would implement Section 6402(a) of the Affordable Care Act (ACA),[3] also known as the "60-day rule," which requires providers, suppliers, Medicare Advantage organizations, prescription drug plan sponsors, and Medicaid managed care organizations to report and return an "overpayment" within the later of (a) 60 days after the overpayment is "identified," or (b) the date any corresponding cost report is due, if applicable. Section 6402(a) defines an "overpayment" as any funds a person receives or retains under Medicare or Medicaid to which the person, after "applicable reconciliation," is not entitled. The 60-day rule applies not only to common claims-related overpayments, such as duplicate billings, but also to claims submitted pursuant to referrals made in violation of the federal Stark and anti-kickback laws. Any overpayment retained after the deadline for reporting and returning an overpayment constitutes an "obligation" for purposes of the federal civil False Claims Act (FCA). A related provision under the ACA also subjects providers who fail to comply with the 60-day rule to potential Medicare and Medicaid exclusion and civil monetary penalties under the federal Civil Monetary Penalty (CMP) statute.

Since its enactment nearly two years ago, the "60-day rule" statute has been a nightmare for providers and their counsel because it contains the toxic mix of vague terms and potentially disastrous consequences for noncompliance. For example, it fails to define several critical concepts, including when an overpayment is "identified" (*i.e.*, when the 60-day clock starts ticking), what constitutes an "applicable reconciliation" process that could delay the "report and return" period (*i.e.*, whether such a process is limited to cost report reconciliation), whether administrative finality under Medicare's reopening regulations affects the definition of an overpayment, the effect of the CMS and Office of Inspector General (OIG) self-disclosure protocols on the 60-day reporting deadline and, while not an ambiguity in the statutory terms, whether and to what extent CMS will apply the 60-day rule to overpayments that predate the effective date of ACA and whether such retrospective application depends on whether the overpayment is discovered before or after the effective date of ACA.

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[1] We use the term "provider" herein to refer to both Medicare providers and suppliers.

[2] 77 Fed. Reg. 9179-9187 (Feb. 16, 2012). Comments are due no later than 5:00 p.m. Eastern time on April 16, 2012.

[3] Section 6402(a) has been codified at 42 U.S.C. § 1320a-7k(d).

While the Proposed Rule, if finalized, would inject some additional certainty into the 60-day rule, it would do so in a manner that would be burdensome for providers, would put providers under intense time and cost pressure, and would do some violence to already settled expectations under the current regulatory scheme. CMS appears to be starting from a position dictated by Department of Justice litigation positions advocated in false claims actions – *e.g.*, defining "identification" as consisting of knowledge of the fact of an overpayment and subjecting providers to a 10-year lookback period in identifying certain claims-based overpayments – and using the 60-day rulemaking comment period to offer the provider community an opportunity to convince CMS why it should apply a less stringent approach. The provider community should seize this opportunity to so comment. The Proposed Rule is also notably silent on important issues, such as how providers should handle a situation where the provider cannot quantify the amount of an overpayment within 60 days; whether providers can use the existing Medicare adjustment bill process to resolve overpayments resulting from claims that are within the 12-month claims correction window; and how CMS will address potential retroactive enforcement issues created by the 10-year lookback period.

This Alert highlights the requirements the Proposed Rule would impose and discusses some of the key legal, operational, and technical issues the Proposed Rule raises and on which providers may want to submit comments.

II. Overview of the Proposed Rule

All Medicare Part A and Part B Providers Affected. The Proposed Rule would implement the 60-day rule only with respect to providers of Medicare Parts A and B items and services. CMS has indicated that it will address the other "persons" subject to the 60-day rule (*i.e.*, Medicaid managed care organizations, Medicare Advantage organizations, and Medicare Part D Plan sponsors) at a later date. However, CMS notes in the preamble to the Proposed Rule (Preamble) that even in the absence of a final regulation, all stakeholders subject to the 60-day rule could face potential FCA and/or CMP liability under existing statutory provisions.

Definitions. The Proposed Rule provides three express definitions – "Medicare contractor," "overpayment," and "person" – that are consistent with existing statutory and regulatory definitions. Other key concepts and terms are defined throughout the 60-day rule regulation itself. The Preamble provides several examples of "overpayments," including:

- Medicare payments for non-covered services
- Medicare payments in excess of the allowable amount for an identified covered service
- Errors and non-reimbursable expenditures in cost reports
- Duplicate payments
- Receipt of Medicare payment when another payor had the primary responsibility for payment

Basic Rule. Under the Proposed Rule, if a person has "identified" that the person has received an overpayment, the person must report and return the overpayment by the later of (i) the date which is 60 days after the date on which the overpayment was identified, or (ii) the date any "corresponding

cost report" is due, if applicable. Any overpayment retained by a person after the applicable deadline would become an "obligation" for purposes of the federal FCA.[4]

"Identification" Defined Broadly to Include Knowledge of the Fact of an Overpayment. The Proposed Rule provides that a person has "identified" an overpayment if the person has "actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment." CMS acknowledges in the Preamble that in some cases, a provider may receive information concerning a potential overpayment that creates an obligation "to make a reasonable inquiry" to determine whether an overpayment exists; failure to make such an inquiry "with all deliberate speed" (perhaps as little as 60 days) could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received an overpayment. Once a potential overpayment has been confirmed, the provider would have 60 days to report and return it. The Preamble provides a non-exhaustive list of examples of when an overpayment has been "identified," including:

- A provider receives an anonymous compliance hotline complaint about a potential overpayment and fails to make a reasonable inquiry into the complaint
- A provider learns that a patient death occurred prior to the service date on a claim that has been submitted for payment
- A provider performs an internal audit and discovers that overpayments exist
- A provider is informed by a government agency of an audit that discovered a potential overpayment, and the provider fails to make a reasonable inquiry

None of these examples distinguishes the "existence" of an overpayment from the ability of the provider to "quantify" the amount of the overpayment for purposes of the definition of "identification" under the statute. Thus, we are concerned that CMS views knowledge of an issue of overpayment as sufficient to begin the 60-day clock, without regard to how long it might reasonably take the provider to determine the correct amount of the overpayment.

"Applicable Reconciliation" Limited to Cost Reports. The Preamble confirms CMS's intent to limit "applicable reconciliation" to cost report reconciliation; i.e., in situations where CMS makes interim payments to a provider throughout the cost reporting year and the provider reconciles those payments with covered and reimbursable costs at the time the cost report is due. Accordingly, the Proposed Rule defines applicable reconciliation as occurring when a cost report is filed, except where the provider either receives updated SSI ratio information, or knows that an outlier reconciliation will be performed, in which cases the provider is not required to return any resulting overpayment until the final reconciliation of the applicable cost report. In addition, the Preamble states that providers may rely on the "applicable reconciliation" cost report deadline only in cases where cost report reconciliation would be relevant to the determination of whether an actual overpayment exists. For example, an overpayment related to graduate medical education (GME) payments must be reported and returned either 60 days after it has been identified or on the date the cost report is due, whichever is later. By contrast, issues involving upcoding must be reported and returned within 60 days of identification, because upcoded claims for payment are not submitted to Medicare in the form of cost reports.

[4] As noted above, retention of an overpayment beyond the applicable 60-day rule deadline also may subject a provider to CMP liability and exclusion from Federal health care programs.

Use of Existing Self-Disclosure Protocols (Mostly) Suspends 60-Day Deadline. In recognition of the interaction between the 60-day rule's obligation to report and return overpayments and existing procedures for providers to self-disclose actual or potential Stark violations to CMS through the Medicare Self-Referral Disclosure Protocol (SRDP), the Proposed Rule suspends the obligation to return overpayments under the 60-day rule when CMS acknowledges receipt of a disclosure made pursuant to the SRDP. Suspension of this obligation continues until CMS enters a settlement agreement with the person, the person withdraws from the SRDP, or the person is removed from the SRDP. However, the Preamble clarifies that SRDP disclosures do not suspend the obligation to report overpayments to the applicable payor. Similarly, CMS has proposed suspending the obligation to return overpayments under the 60-day rule when OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol (SDP), which enables providers to self-disclose evidence of potential fraud to OIG. As with SRDP submissions, suspension of this obligation continues until OIG enters a settlement agreement with the person, the person withdraws from the SDP, or the person is removed from the SDP. Unlike SRDP submissions, however, the Proposed Rule characterizes a disclosure under the SDP as a report for purposes of the 60-day rule's reporting requirements (although the provider still must make the SDP disclosure in accordance of the 60-day rule's timeliness requirements), and so providers who receive OIG acknowledgment of receipt for SDP disclosures would not be required to make a separate report of the overpayment.

Overpayment Reports Rely on Existing Voluntary Refund Processes, But Must Contain Specified Elements. Under the Proposed Rule, a provider who identifies an overpayment must make a written report to the applicable payor that contains all of thirteen specified elements, including: (1) the person's name; (2) the person's tax identification number; (3) how the error was discovered; (4) the reason for the overpayment; (5) the health insurance claim number (as appropriate); (6) the date of service; (7) the Medicare claim control number (as appropriate); (8) Medicare National Provider Identification (NPI) number; (9) a description of the corrective action plan to ensure the error does not occur again; (10) whether the provider has a corporate integrity agreement with OIG or is under the OIG's SDP; (11) the timeframe and total amount of the refund for the period during which the problem existed that cause the refund; (12) if a statistical sample was used to determine the overpayment amount, a description of the statistically valid methodology used to determine the overpayment; and (13) a refund in the amount of the overpayment.

The Preamble notes that CMS intends to use the "existing voluntary refund process," which will be renamed the "self-reported overpayment refund process," to implement the 60-day rule. Under this process, CMS intends for providers to report overpayments using a form that Medicare contractors make available on their websites.[5] Accordingly, the Proposed Rule requires that except for persons who have satisfied the reporting requirement through making a disclosure under the OIG SDP and entering into a settlement agreement under the SDP, persons subject to the 60-day rule must use the self-reported overpayment refund process set forth by the applicable Medicare contractor to report

[5] *See*, *e.g.*, Palmetto GBA Medicare, Overpayment Refund Form: Medicare Part A and B, *at* http://www.palmettogba.com/Palmetto/Providers.Nsf/files/J1_overpayment_refund_form_revised.pdf/$File/J1_overpayment_refund_form_revised.pdf (last accessed Feb. 15, 2012).

and return overpayments.[6] Consistent with this approach, the Proposed Rule provides that a person may request an "extended repayment schedule" (ERS) when submitting an overpayment report, and that the ERS is "the only means by which extended repayment of an overpayment will be permitted." The Preamble notes that CMS included this provision in recognition of concerns over scenarios in which a provider has identified an overpayment, but because of the magnitude of the overpayment, needs additional time to make repayment. CMS cautions that providers may not delay the identification date in these scenarios, but rather must use the existing ERS process as outlined in the Medicare Financial Management Manual. In addition, the Preamble warns providers that requests for ERS "are not automatically granted," and that providers seeking to avail themselves of this process will be required to submit "significant documentation" to support a claim that timely repayment of the overpayment represents a "true financial hardship" for the provider.[7]

Ten-Year Lookback and Claims Reopening Periods. The Proposed Rule provides that an overpayment must be reported and returned if a person identifies the overpayment "within 10 years of the date the overpayment was received." The Preamble indicates that CMS chose a 10-year lookback period because this is the outer limit of the federal FCA statute of limitations, and believes this period is appropriate because providers and suppliers "should have certainty after a reasonable period that they can close their books and not have ongoing liability associated with an overpayment." In connection with the 10-year lookback period, the Proposed Rule amends the Medicare claims reopening rules to provide that overpayments reported under the 60-day rule implementing regulations may be reopened for a period of 10 years from the date of initial determination or redetermination. There is no corresponding proposed amendment to the notice of program reimbursement (NPR) determination regulatory reopening period, which remains three years. Thus, it seems to us that the lookback period for cost reporting issues remains at three years from an NPR, absent fraud or similar fault, which tolls the running of that three-year period.

CMS Estimates Low Compliance Burden. Finally, the Preamble estimates that approximately 8.5% of the total number of Medicare providers will report and return overpayments in a typical year under the Proposed Rule, and that each of these providers would report and return approximately three to five overpayments at a total time investment of 2.5 hours per overpayment to complete the applicable reporting form and return the overpayment. The Preamble notes that CMS assumes two categories of individuals will be involved in completing and submitting the applicable reporting form – accountants and auditors (both external and in-house), and "miscellaneous in-house administrative personnel." Based on these assumptions, CMS calculates a combined mean hourly wage of $37.10 per hour, for a total estimate compliance cost of approximately $92.75 per overpayment, or approximately $278.25 - $463.75 per provider per year. These estimates appear to be unrealistically low, given the complexity providers and their counsel frequently encounter investigating and analyzing whether there has been an overpayment, and then calculating the amount of the overpayment.

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[6] The Preamble recognizes that different Medicare contractors may have different forms, and notes that CMS plans to develop a uniform reporting form that will enable all overpayments to be reported and returned in a consistent manner.

[7] In connection with CMS's intent to permit use of ERS requests in the overpayment reporting process, the Proposed Rule amends the definition of "hardship" in the Medicare claims collection regulations to include overpayments reported under the 60-day rule implementing regulations.

III. Challenges for Providers under the Proposed Rule

The Proposed Rule presents several significant operational, technical, and legal issues upon which providers may wish to comment.

"Identification" Standard Disregards Difficulties in Quantifying Amount of Overpayment. Perhaps the most significant "report and return" issue the Proposed Rule raises is the definition of "identification" as including actual knowledge, deliberate ignorance, or reckless disregard of the "existence of an overpayment," without regard to a provider's ability to quantify the amount of the overpayment. In a surprising omission, the Proposed Rule is wholly silent about how a provider should handle the situation where it knows that it has been overpaid, but cannot quantify the overpayment within 60 days (even with reasonable diligence). A provider's inability to quantify an overpayment within 60 days apparently would not diminish the provider's obligation to report and return it within that time-frame, even though CMS insists that one of the elements that the provider must include in the report is the "total amount of the refund."

As noted above, following the passage of the ACA and the "60-day rule" statute, the provider community was left to fend for itself in determining what it meant to "identify" an overpayment. In the absence of guidance from CMS, various views emerged regarding an "appropriate" interpretation of the 60-day rule. These views ranged from viewing any notice of the existence of a potential overpayment as constituting "identification" (the "whiff test"), to requiring actual knowledge of both the existence and full amount of the overpayment and the absence of any good-faith counterarguments to the provider's entitlement to payment before an overpayment is "identified," to somewhere in between.

The Proposed Rule adopts an expansive approach to "identification" – essentially the "whiff test." Accordingly, the Proposed Rule would place significant pressure on a provider's internal reporting capabilities and ability to conduct relatively rapid investigations of any potential indication that an overpayment may have occurred. The use in the Proposed Rule of the federal FCA's actual knowledge/deliberate ignorance or reckless disregard standard, while not equivalent to a "knew or should have known" standard, raises the possibility that the government may come in behind a provider and second-guess whether a provider exercised "reasonable diligence" and made a "reasonable inquiry" "with all deliberate speed" in determining when an overpayment should have been identified.

If the Proposed Rule's definition of "identification" is finalized, providers will probably need to run their factual and legal processes concurrently following any initial credible suggestion of a potential overpayment and resolve the issue during the following 60 days. To the extent the investigation takes longer than 60 days, the provider would seem to be at some enforcement risk if an overpayment is ultimately found, although providers possibly could mitigate this risk through a compelling and documented basis for extending the investigation/resolution process past 60 days. The Proposed Rule is silent, however, regarding whether and to what extent CMS would accept an investigation that extends beyond 60 days. This time pressure, combined with serious consequences for noncompliance, may force providers to err on the side of disclosing potential overpayments, which could increase both the volume of overpayment reporting, as well as the time and cost associated with such reports, and could result in the return of funds that are ultimately found not to have been overpayments.

Proposed Rule Does Not Address Use of Claims Correction Processes. In another surprising omission, the Proposed Rule does not discuss whether providers can use Medicare's existing adjustment bill/claims correction processes to resolve overpayments resulting from claims that are identified within the one-year claims correction window, or whether providers must report and repay such overpayments using the regulatory process set forth in the Proposed Rule. Many providers have relied on Medicare's existing claims correction processes to adjust overpayments without resorting to the 60-day rule's report and refund provisions, and this approach has enabled quick and relatively inexpensive resolution of such overpayments. Given the Proposed Rule's ostensible goal of relying on existing processes in implementing the 60-day rule (*e.g.*, the voluntary refund and ERS request processes), it would be alarming if CMS precluded providers from utilizing existing Medicare claims correction processes to resolve overpayments where the claims are within the one-year resubmission window. Despite this conflict, the Proposed Rule provides no guidance on this issue, and so it is unclear whether CMS intends to prohibit providers from using the long-standing claims correction process under the 60-day rule implementing regulations.

10-Year Lookback Period Raises Retroactivity Issues. Finally, the Proposed Rule's expansive 10-year lookback period and corresponding amendments to the Medicare claims reopening regulation raise significant questions regarding retroactive application of the 60-day rule. For example, it is unclear whether the sanctions enacted under the ACA for failure to report and repay an overpayment within the 60-day rule's deadlines will apply to overpayments identified before March 23, 2010 (*i.e.*, the ACA's passage). Because these sanctions attached to retention of an identified overpayment beyond 60 days, CMS might interpret the 60-day rule to require all overpayments identified prior to March 23, 2010 to have been reported and repaid within 60 days of the ACA's passage (*i.e.*, under a "continuing violation" theory). However, such an interpretation would conflict with existing case law and arguably could conflict with Medicare's "without fault" rules. It is also unclear from the language of Section 6402(a) of the ACA where Congress provided CMS with the authority to extend retroactively the time limit under the Medicare reopening regulation from four to 10 years. Such retroactive application would violate the "settled expectations" test for permissible retroactivity. Finally, it seems an inequitable result for CMS to impose a 10-year lookback period for identifying overpayments without creating a parallel offset for identifying underpayments. In any event, the Proposed Rule is silent regarding the retroactive application of the 60-day rule and how CMS will interpret these significant legal issues.

IV. Conclusions and Next Steps for Providers

If the regulations implementing the 60-day rule are finalized as currently proposed, CMS's approach to interpreting the 60-day rule will create intense time pressure for providers and will significantly increase the operational, and potentially financial, burdens of overpayment disclosure.

The Proposed Rule's definition of "identification" as consisting of a provider's knowledge of the existence of an overpayment places significant emphasis on the strength of a provider's internal controls and compliance program, and the ability to move fast. Given the time constraints and serious penalties associated with the 60-day rule, providers would be well-served to review their internal overpayment identification and escalation processes to ensure that providers have the systems in place to quickly identify and analyze potential overpayments, including the engagement of experienced in-house and outside counsel as appropriate.

In addition, while the Proposed Rule provides a degree of additional clarity surrounding the application of the 60-day rule, the Proposed Rule is also notable in its silences – particularly with

respect to the common and well-known issues surrounding difficulties in quantifying overpayments within 60 days and reliance on the existing Medicare claims correction process to address overpayments within the one-year resubmission window. We can only assume that CMS's silence constitutes an invitation for the provider community to offer comments and suggestions about how CMS might approach these issues – an invitation the provider community should enthusiastically accept.

Although the Proposed Rule is limited to Medicare Part A and Part B providers and suppliers, CMS likely will interpret and enforce the 60-day rule against all "persons" in a manner generally consistent with the Proposed Rule once it is finalized. Accordingly, all stakeholders subject to the 60-day rule have a vested interest in the shape the final regulations will take. Hopefully, CMS will be receptive to comments from the provider community regarding the Proposed Rule and will take them into account while providing further guidance and clarity in the final rule.

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