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The Medicare Overpayment Rule: Implications for Compliance and Health Care Enforcement

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As has been widely discussed, the Centers for Medicare & Medicaid Services (''CMS'') Feb. 12 published the long-awaited final rule governing the return of Medicare Part A and Part B overpayments within 60 days (the ''Overpayment Rule'').[1]

The Overpayment Rule implements Section 6402(a) of the Affordable Care Act, which established section 1128J(d) of the Social Security Act (the ''Act''). The Act requires that an overpayment be reported and returned 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).

The proposed rule,[2] which was published four years ago, led to a great deal of consternation among providers and suppliers, and thus it is no surprise that CMS received over 200 comments.

In the final Overpayment Rule, CMS addressed many stakeholder concerns, and the Overpayment Rule provides a more workable approach than the proposed rule.

Without doubt, though, CMS specifies in the Overpayment Rule that it expects providers and suppliers to have a proactive compliance program designed to monitor for potential overpayments and to timely investigate credible information that an overpayment has been received.

Compliance with the Overpayment Rule is crucial because the potential penalties for non-compliance could be ruinous. Providers and suppliers who fail to timely identify and return overpayments face potential liability under the Civil Monetary Penalties Law as well as exclusion from the federal health care programs.

In addition, under the False Claims Act (''FCA''), retaining an overpayment is defined as an ''obligation,'' and ''knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation'' can be the basis for treble damages and penalties under the FCA (often called ''reverse'' FCA liability).[3]

Below, we describe several key aspects of the Overpayment Rule, identify a number of open questions, and

[1] Medicare Program; Reporting and Returning of Overpayments; Final Rule, 81 Fed. Reg. 7654 (Feb. 12, 2016).

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[2] Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179 (Feb. 16, 2012).

[3] 31 U.S.C. § 3729(a)(1)(G).

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discuss the Overpayment Rule's implications for health care fraud enforcement and compliance.

Key Provisions and Open Questions

Several provisions of the Overpayment Rule will drive providers and suppliers' efforts to comply with its requirements.

1. The term "identified" requires both a determination of the overpayment and "quantification" of the amount of the overpayment. The meaning of the phrase ''identified an overpayment'' determines when the 60-day clock starts to run. CMS stated in the Overpayment Rule that a provider or supplier has identified an overpayment if it: (1) ''has, or *should have* through the exercise of *reasonable diligence*, determined that [it] has received an overpayment''; and (2) has ''quantified the amount of the overpayment.''[4] To prevent the so-called ostrich defense, CMS said in the Overpayment Rule that providers and suppliers ''should have'' identified and quantified an overpayment ''if the person *fails to exercise reasonable diligence* and the person in fact received an overpayment.''[5]

Several aspects of CMS's definition of the term ''identified'' will impact how providers and suppliers must monitor, investigate, quantify, and report overpayments.

a. The "reasonable diligence" standard. The Overpayment Rule makes ''reasonable diligence'' the touchstone of providers' and suppliers' obligations. According to CMS, reasonable diligence requires both proactive compliance measures (conducted in good faith by qualified individuals) to monitor for potential overpayments and investigations of ''credible information'' of a potential overpayment.[6]

i. Reasonable diligence requires proactive compliance efforts. CMS made clear that proactive compliance efforts are required and that ''undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims'' may expose a provider or supplier to liability for failure to exercise reasonable diligence.[7]

CMS declined, however, to provide specific guidance on the compliance processes required to comply with the Overpayment Rule; instead, CMS pointed to the resources available through the Medicare Learning Network and the compliance educational material on OIG's website. CMS may not have provided specific compliance guidance because it acknowledged that compliance programs need not be uniform and may vary based on the size and complexity of a provider's or supplier's operations. The preamble explains that compliance programs may vary ''in size and scope and that compliance activities in a smaller setting, such as a solo practitioner's office, may look very different than those in larger setting, such as a multi-specialty group. Compliance activities may also appropriately vary based on the type of provider.''[8]

ii. Reasonable diligence requires investigations into ''credible information'' of an overpayment. CMS also requires a timely, good-faith investigation into ''credible information'' of a potential overpayment. Absent ''extraordinary circumstances,'' CMS opined that the investigation should not exceed six months.[9] The six-month timeframe may be difficult to meet, especially given that the Overpayment Rule requires analysis of six years of data through the six-year look-back period (discussed below). This is especially true where matters require internal investigation and legal analysis, as well as investigations involving cost report issues and other complex quantifications.

What constitutes ''extraordinary circumstances'' is not defined, although CMS provided some examples: physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol (''SRDP''), natural disasters, and states of emergency. In addition to the lack of guidance about what ''extraordinary circumstances'' are, the Overpayment Rule does not explain what steps providers and suppliers should take if they encounter ''extraordinary circumstances.'' At a minimum, though, providers and suppliers who encounter what they reasonably consider ''extraordinary circumstances'' should carefully document their overpayment investigation as well as the facts and circumstances that give rise to the extraordinary circumstances.

b. Quantification of an overpayment must be complete before an overpayment has been "identified." In addition, the Overpayment Rule includes quantifying the overpayment amount as a necessary part of identifying an overpayment. Thus the 60-day ''clock'' does not begin until an overpayment has been quantified. This is a significant change from the proposed rule because it accounts for the difference between determining that an overpayment had been received and the audit work necessary to quantify the overpayment amount, which takes time. Moreover, the Overpayment Rule makes clear that the overpayment amount may be determined by employing frequently used methods such as statistical sampling and extrapolation. The methodology used to quantify and overpayment must be disclosed.

2. CMS reduced the "look back" period from 10 years in the proposed rule to 6 years in the final Overpayment Rule. CMS reduced the look-back period to six years. According to CMS, this timeframe is practical because it aligns with the FCA statute of limitations, and providers and suppliers commonly retain records for six to seven years based on state and federal requirements.

Providers and suppliers may be disappointed that CMS changed the look-back time period from four years to six years for overpayments based on Stark Law violations submitted through the SRDP after the Overpayment Rule's effective date. Although six years remains a long look-back time period, the burden on providers and suppliers is less than if CMS retained a 10-year look back time period.

3. The re-opening deadlines are a one-way street. The Overpayment Rule amends the rules allowing for a request to a Medicare contractor to reopen initial determinations to permit reporting and returning overpayments.[10] However, the Overpayment Rule does not per-

[4] 81 Fed. Reg. at 7683 (emphasis added).
[5] 81 Fed. Reg. at 7683 (emphasis added).
[6] *Id*. at 7662.
[7] *Id*. at 7661.
[8] *Id*.
[9] *Id*. at 7662.
[10] 42 C.F.R. § 405.980(c)(4).

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mit identification and claiming of underpayments for the same six-year period. In fact, CMS declined to allow providers and suppliers more than the current one-year period to rebill a claim to correct an identified underpayment. Moreover, the Overpayment Rule does not allow netting of underpayments against overpayments. CMS declared that underpayment issues are outside the scope of this rulemaking.

4. Existing processes should be used to report and return overpayments. In response to comments advocating reliance on existing processes to return overpayments, CMS allowed for the use of applicable claims adjustment, credit balance, self-reported refund, or other reporting processes established by the applicable Medicare contractor to report an overpayment. In addition, providers and suppliers, where appropriate, satisfy their 60-day reporting obligations by utilizing the disclosure processes in the OIG Self-Disclosure Protocol (''SDP'') or CMS's SRDP, as applicable.

The Overpayment Rule also removed the 13 elements of an overpayment report that CMS included in the proposed rule. For example, under the proposed rule, a report had to provide a description of how the error was identified and the reason for the overpayment. That information is no longer required by the Overpayment Rule (but may be required by the Medicare contractor's existing processes or through the SDP or SRDP).

5. Healthcare fraud enforcement based on the Overpayment Rule. Because retaining an overpayment beyond 60 days is a basis for FCA liability, the Overpayment Rule may become fertile ground for *qui tam* relators. Because certain concepts in the Overpayment Rule such as ''reasonable diligence'' and quantification of an overpayment are flexible concepts, whether these standards have been met in a particular circumstance might be subject to interpretation and potential challenge by relators, who are often employees and contractors. Indeed, some *qui tam* lawsuits alleging FCA liability based on retaining overpayments have started to emerge.[11] It will be potentially burdensome for providers and suppliers to respond to government investigations resulting from *qui tam* complaints.

a. It is unclear whether reporting and returning an overpayment is a public disclosure barring qui tam FCA lawsuits. The preamble to the Overpayment Rule includes a notable discussion regarding the FCA. Although commenters requested confirmation that a report of an overpayment is a ''public disclosure'' under the FCA and therefore bars liability under the FCA's *qui tam* provisions, CMS (not surprisingly) did not respond substantively, explaining that it is interpreting Section 1128J, not the FCA.[12] Thus, the Overpayment Rule offers no guidance on whether returning and reporting an overpayment precludes a *qui tam* FCA claim alleging facts that are the same as, or similar to, the basis for the overpayment.

b. The Overpayment Rule and liability under the AKS and FCA. In addition, enforcement efforts regarding overpayments for Medicare claims allegedly tainted by federal Anti-Kickback Statute (''AKS'') violations will be an area to monitor. Since at least 2010, through an amendment to the AKS, claims for payment ''resulting from'' AKS violations constitute ''false or fraudulent'' claims under the FCA. Now, according to CMS, Medicare claims that result from AKS violations also may be overpayments and thus a basis for ''reverse'' false claims liability under the FCA.

In the preamble to the Overpayment Rule, CMS stated that ''there are instances where payment is made for an item or service specifically not payable under the Act (for example, claims resulting from [AKS] or physician self-referral law violations . . .), or where the payment was secured through fraud. In these types of situations, *the overpayment typically consists of the entire amount paid*.''[13] CMS's basis for this position is that ''[c]ompliance with the [AKS] is a condition of [Medicare] payment.''[14] *Qui tam* relators may advance the theory that claims resulting from alleged AKS violations are overpayments and thus a basis for FCA liability.

c. Kickback arrangements and ''innocent'' third parties. The preamble to the Overpayment Rule also addresses the obligations of an innocent third party to a kickback arrangement to report an AKS-based overpayment. For example, a hospital may submit claims for a physician who received alleged kickbacks from a pharmaceutical company and the hospital has no knowledge of an alleged kickback. CMS explained that, ''providers and suppliers who are not a party to a kickback arrangement are unlikely in most instances to have 'identified' an overpayment that has resulted from the kickback arrangement and would therefore have no duty to report or return it.''[15] However, if a provider or supplier has received an overpayment resulting from a kickback arrangement—and is not a party to a kickback arrangement—but ''has ***sufficient knowledge*** of the arrangement to have identified the resulting overpayment, the provider or supplier must report the overpayment to CMS.''[16] Whether a provider or supplier has ''sufficient knowledge'' of an alleged kickback varies based on the facts and circumstances and may be the subject of *qui tam* lawsuits.

6. Steps that providers and suppliers should consider taking to comply with the Overpayment Rule. Providers and suppliers can take some reasonable steps to comply with, and to demonstrate compliance with, the Overpayment Rule.

■ *Assess compliance programs*—Assess compliance programs to validate whether proper processes are in place to identify possible overpayments in a timely way.

■ *Establish protocols for investigation and quantification*—Establish protocols, or review existing protocols, to conduct reasonable diligence to investigate possible overpayments and to quantify overpayments in a timely manner as CMS has established a six-month time period as the standard.

■ *Maintain documentation*—Document investigations of potential overpayment to demonstrate reason-

[11] *E.g.*,*United States ex rel. Kane v. Healthfirst, Inc.*, 2015 BL 249012 (S.D.N.Y. 2015) (finding that identification occurs when ''a person is put on notice that a certain claim may have been overpaid.''); In *United States ex rel. Keltner v. Lakeshore Med. Clinic, Ltd.*, 2013 BL 83984 (E.D. Wis. 2013).

[12] 81 Fed. Reg. at 7665.

[13] *Id*. at 7658 (emphasis added).

[14] *Id*. at 7659.

[15] *Id*. at 7666.

[16] *Id*.

able diligence to investigate and quantify a potential overpayments (while carefully maintaining and protecting the attorney-client privilege), including documenting the timing of investigatory steps. Indeed, CMS explained that ''it is certainly advisable for providers and suppliers to maintain records that accurately document their reasonable diligence efforts to be able to demonstrate their compliance with the rule.''[17]

■ *Carefully track timing*—Document the timeline of investigations from the ''credible information'' of a potential overpayment, to the verification of an overpayment and quantification of it to ensure clarity about when, under the provider's circumstances, the 60-day clock starts running. Most importantly, document when the 60-day clock starts running and what event triggered it.

[17] *Id*. at 7662.

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