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CMS's Final Rule Implementing the 60-Day Report and Return Statute for Medicare Parts A and B Significantly Broadens the Scope of Overpayments and the Duty of Providers to Identify Them



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I. Introduction

On Feb. 12, 2016, the Centers for Medicare & Medicaid Services (CMS) published its long-awaited final rule (the “Final Rule”) regarding the obligations of Medicare providers¹ to report and return overpayments arising under Medicare Parts A and B.² The Final Rule, which was effective March 14, 2016, implements § 6402(a) of the Affordable Care Act (ACA), also

¹ In this article, unless the context requires otherwise, the term “providers” includes suppliers.

² 81 Fed. Reg. 7654 – 7684 (Feb. 12, 2016).

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known as the “60-day report and return statute,” which requires providers, Medicare Advantage organizations, prescription drug plan sponsors, and Medicaid managed care organizations to report and return Medicare and Medicaid overpayments within the later of (a) 60 days after the overpayment is “identified,” or (b) the date any corresponding cost report is due, if applicable.³ The notice of proposed rulemaking (“the Proposed Rule”) was published on Feb. 16, 2012.⁴

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 report and return statute applies not only to common claims-related overpayments, such as duplicate billings, and cost report errors that result in an overpayment, but also to claims submitted pursuant to referrals made in violation of the federal Stark and anti-kickback laws. Any overpayment impermissibly retained under this statute constitutes an “obligation” for purposes of the federal civil False Claims Act (FCA).⁵ A related ACA provision also subjects providers who fail to comply with this statute to potential Medicare and Medicaid program exclusion and penalties under the federal Civil Monetary Penalty (CMP) statute.⁶

Since its enactment in March 2010, the 60-day report and return statute has been a nightmare for providers and their counsel because it contains the toxic mix of

³ Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, Title VI, § 6402(a), 124 Stat. 119, 753 – 756, codified at 42 U.S.C. § 1320a-7k(d).

⁴ 77 Fed. Reg. 9179 – 9187 (Feb. 16, 2012).

⁵ 31 U.S.C. § 3729 *et seq.*

⁶ 42 U.S.C. § 1320a-7a(a)(10).

vague terms, operational challenges, and potentially disastrous consequences for noncompliance. For example, the statute does not 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 how far back providers must go when calculating overpayments.

Interpretations of these and other concepts under the 60-day report and return statute have varied widely; providers attempting to comply with this statute often have ended up submitting their best guess at a compliant overpayment report and refund to their Medicare Administrative Contractor (MAC) (or other applicable entity) and then adopting a “cross your fingers” approach to see whether the MAC agrees with the substance of the disclosure (often with no response). Such uncertainty has created significant compliance challenges and has caused providers to incur substantial time and expense in determining the reach of the statute, investigating whether an overpayment has occurred, and drafting overpayment disclosures, particularly in areas where the underlying payment rules may not be clear.

The Final Rule provides needed clarity on some aspects of the 60-day report and return statute and fills many gaps left unaddressed in the statute and Proposed Rule. For example, previously unaddressed was the effect on “identification” of a provider’s inability to quantify an overpayment with reasonable precision. The Proposed Rule noted only that difficulties in quantification would not delay the starting of the 60-day clock. Responding to provider concerns, the Final Rule helpfully notes that quantification is a part of the identification process, such that a diligently investigated overpayment would not be said to have been identified until quantified. At the same time, however, the preamble to the Final Rule provides a benchmark or outer limit for how long identification (including quantification) of an overpayment should reasonably take.

At bottom, however, the Final Rule, which affects virtually every Medicare provider, is a mixed bag. While providing guidance for the diligent to mitigate risk to some extent, it actually perpetuates significant uncertainty by relying on several vague but essential terms, such as “reasonable diligence,” “proactive compliance,” and “credible information.” These important terms, which are peppered throughout the Final Rule, turn compliance even more into a legal process.

CMS also put the onus on providers to determine how to apply these terms (without the benefit of deference and without a minimum overpayment materiality threshold), knowing that the government and the FCA bar will be looking over their shoulders. This is because the Final Rule makes clear that the buck for reporting and returning overpayments stops at providers, even potentially where the provider was not responsible for the overpayment. While CMS’s position is in some ways understandable because the provider received the payment, it will often require a provider to clean up, at the provider’s expense, a mess made by another. Moreover,

failure to strictly comply with the Final Rule can create substantial exposure, not only for overpayments but also for CMPs, federal program exclusion, and litigation costs and liability under the FCA.

Despite the many helpful clarifications in the Final Rule, compliance with the 60-day report and return statute continues to be a nightmare of vague terms and potentially disastrous consequences, albeit for slightly different reasons. As regulators and courts consider enforcement of this beguiling statute, it is essential that they remain mindful that CMS *purposefully* used vague terms in the Final Rule so as to allow application of its terms to evolve over time, seasoned by experience with real-life circumstances, thereby giving providers proper advanced notice of how these terms will be applied.⁷ Inflexible application of these vague terms would not only be inconsistent with the approach taken in the Final Rule, but also deeply unfair.

This article summarizes the provisions of the Final Rule and discusses some of its key legal, operational, and technical “takeaways” for providers.

II. Summary of the Final Rule

A. Scope of the Final Rule—Medicare Parts A and B

The Final Rule implements the 60-day report and return statute with respect to providers of Medicare Parts A and B items and services. CMS previously issued a final rule for Medicare Parts C and D on May 23, 2014.⁸ CMS has yet to initiate rulemaking with regard to the application of the 60-day report and return statute to Medicaid overpayments. So, while there is no directly applicable federal authority beyond the statute, it is important to check state law for authorities addressing Medicaid overpayment requirements.

The Final Rule adds the following new regulations: 42 C.F.R. §§ 401.301, 303, and 305, § 401.607(c)(2)(i), and § 405.980(c)(4). These new regulations do not fill even one page of the Final Rule. The other 29 pages contain extensive explanation of the overpayment refund process and how it may apply in several substantive circumstances. Thus, knowledge of the overpayment regulations is not sufficient—providers also need to be familiar with the details presented in the preamble of the Final Rule.

B. Reasonable Diligence Standard (81 Fed. Reg. at 7659 – 61)

In the Proposed Rule, borrowing the FCA standard, CMS stated that a provider had identified an overpayment if the provider had actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. CMS justified this approach, in part, by noting that the statute in-

⁷ On a number of occasions in the preamble to the Final Rule, CMS reminds readers that key terms and obligations are defined by the relevant facts and circumstances present in an individual case. *E.g.*, 81 Fed. Reg. at 7657 – 58 (facts and circumstances test for determining whether an overpayment exists); *id.* at 7662 (whether extraordinary circumstances justify a longer period of investigation turns on the facts); *id.* at 7662 (reasonable diligence is a “fact-dependent” inquiry); *id.* at 7666 (facts and circumstances test for credible information).

⁸ 79 Fed. Reg. 29844 (May 23, 2014).

cludes the FCA definitions of the terms “knowing” and “knowingly.” CMS has acknowledged that the text of the 60-day report and return statute does not use these terms, and the inclusion of definitions of these terms was an error in the legislative process. CMS nevertheless asserted in the Proposed Rule that the reference to these terms was intended to apply to determining when a provider has identified an overpayment.

CMS also stated in the Proposed Rule that defining “identification” in this way gives providers an incentive to exercise reasonable diligence to determine whether an overpayment exists. Without such a definition, CMS expressed concern that providers might avoid performing proactive activities that might identify overpayments, such as self-audits and compliance checks.

CMS also indicated in the Proposed Rule that there may be occasions when a provider receives information concerning a potential overpayment that creates a duty to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider would then have 60 days to report and return the overpayment. On the other hand, the failure to make a reasonable inquiry, including failure to conduct such inquiry with “all deliberate speed” after obtaining the information, could result in the provider “knowingly” retaining an overpayment by acting in reckless disregard or deliberate ignorance of whether it received an overpayment. CMS set forth a number of examples in the Proposed Rule whereby a duty to timely investigate might exist as a result of credible information of a potential overpayment. These examples provided some useful insights but also prompted many comments.

In the Final Rule, despite continuing to assert that its interpretation in the Proposed Rule was appropriate, CMS changed course by eliminating the use of the FCA-borrowed terms “actual knowledge,” “reckless disregard,” and “deliberate ignorance.” Instead, the Final Rule states that a provider has identified an overpayment when the provider has, or should have through the exercise of “reasonable diligence,” determined that the provider has received an overpayment and quantified the amount of the overpayment.⁹ While “reasonable diligence” is not defined in the regulation, CMS explained in the preamble to the Final Rule that “reasonable diligence” includes (1) *proactive compliance activities* conducted in good faith by qualified individuals to monitor for the receipt of overpayments, and (2) investigations conducted in good faith and in a timely manner by qualified individuals *in response to obtaining credible information* of a potential overpayment.¹⁰

Although providers have long understood the need to investigate credible information of a known or potential overpayment, the reference to “proactive compliance activities” breaks new ground in the overpayment refund arena. By doing so, the Final Rule raises the ante on what it means for a provider to have an effective compliance program and exposes a provider to liability as a result of undertaking no or minimal effort to monitor the accuracy and appropriateness of a provider’s Medicare claims. Lest there be any doubt, the Final Rule states that providers have a “clear duty” to undertake proactive compliance activities to determine if they

have received an overpayment or risk potential liability for retaining such overpayment.¹¹

Some commenters expressed concern that the Proposed Rule’s definition of “identified” opened up the possibility that CMS, other regulators, or qui tam relators could second-guess the provider and question whether the provider exercised reasonable diligence in assessing an overpayment. CMS responded in the Final Rule that it has long been true that many activities in the provision of health care, including billing the Medicare program, are subject to review by various stakeholders.¹² CMS continued that the 60-day report and return statute does not change that situation or significantly expand the areas that have long been subject to such review.¹³

The Final Rule provides no solicitude for small providers. When asked by commenters to provide compliance guidance and clarify the level of resources a small provider is expected to devote to investigating potential overpayments, CMS responded that “we are unable to provide specific guidance on resource levels or other measures to ensure compliance with this rule. Providers and suppliers, large and small, have a duty to ensure their claims to Medicare are accurate and appropriate and to report and return overpayments they have received.”¹⁴ CMS did, however, observe that “compliance programs are not uniform 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 [a] larger setting, such as a multi-specialty group.”¹⁵

Finally, CMS cautions that providers should maintain records that accurately document their reasonable diligence efforts to be able to demonstrate their compliance with the Final Rule.¹⁶

C. Time to Conduct a Reasonably Diligent Investigation (81 Fed. Reg. at 7661 – 62)

In response to comments concerning whether the Proposed Rule would permit time for a reasonable inquiry before the 60-day clock begins ticking, CMS explained in the Final Rule that the duty for a provider to determine whether an overpayment has been received, and to quantify the amount, arises when a provider gets “credible information” that a potential overpayment exists. The 60-day time period will begin when (1) the investigation conducted with reasonable diligence has been completed or (2) on the day the provider received credible information of a potential overpayment, if the provider failed to exercise reasonable diligence (if the provider in fact received an overpayment).¹⁷

¹¹ *Id.* at 7665. CMS declined to address whether reporting of the overpayment should result in a “public disclosure” under the FCA.

¹² *Id.* at 7664.

¹³ *Id.* We also note that CMS encourages providers to report any identity theft to law enforcement and CMS and should wait for instructions from CMS concerning returning the related overpayment. 81 Fed. Reg. at 7666.

¹⁴ *Id.* at 7665.

¹⁵ *Id.* at 7661.

¹⁶ *Id.* at 7662.

¹⁷ *Id.* at 7661. The Final Rule helpfully clarifies that a failure to be “reasonably diligent” with regard to investigating credible information about a potential overpayment does not, by itself, create liability under the 60-day statute: There must be an underlying overpayment that the provider failed to report and return.

⁹ 81 Fed. Reg. at 7661; 42 C.F.R. § 401.305(a)(2).

¹⁰ 81 Fed. Reg. at 7661.

This is also a change from the preamble to the Proposed Rule, which had instructed providers to conclude investigations into potential overpayments with “all deliberate speed.” CMS abandoned the term “all deliberate speed” in the Final Rule, favoring “reasonable diligence.” CMS went on to explain that “reasonable diligence” is demonstrated through the timely, good faith investigation of credible information of an overpayment, which should take no more than six months, except under “extraordinary circumstances.”¹⁸ Moreover, CMS stated in the Final Rule that “part of identification is quantifying the amount, which requires a reasonably diligent investigation.” Thus, the Final Rule clarifies that quantification is part of the identification process that must be present to start the 60-day repayment clock for a reasonably diligent provider.¹⁹

In setting the six-month benchmark, CMS stated its belief that receiving overpayments from Medicare is sufficiently important such that providers should devote appropriate attention to resolving these matters within eight months (six months for timely investigation and two months for reporting and returning), absent “extraordinary circumstances.”²⁰ What constitutes extraordinary circumstances is a fact-specific question but that could include an unusually complex investigation, such as physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). Extraordinary circumstances also could arise where a provider is faced with a natural disaster or state of emergency. Thus, “extraordinary circumstances” is another vague term that will only become clear over time.

D. The “Credible Information” Standard (81 Fed. Reg. at 7662 – 63, 7665)

“Credible information” of an overpayment includes information that supports a reasonable belief that an overpayment may have been received.²¹ CMS believes this standard addresses commenter concerns of being forced to investigate every instance or complaint concerning a potential overpayment. CMS acknowledges that not all information received will be credible and that determining whether information is sufficiently credible to merit an investigation is a fact-specific determination.²²

While what constitutes credible information is a fact-specific inquiry, CMS explained that receiving repeated hotline complaints about the same or similar issues is an example of an instance where a reasonable person may conclude that a provider has received credible evidence warranting reasonable diligence.²³ A single hotline complaint, as CMS also described, could be detailed enough to lead a reasonable person to the same conclusion.²⁴ CMS also explained in the Final Rule that receiving the results of a contractor or government audit is an example of credible information of a potential overpayment that requires the provider to conduct reasonable diligence to confirm or contest the audit’s findings and determine if the practice that resulted in the

overpayment also occurred outside of the audited timeframe.²⁵

CMS explained that the 60-day time period begins either when the reasonable diligence is completed and the overpayment is identified or on the day the person received credible information of a potential overpayment if the person fails to conduct reasonable diligence and the person, in fact, received an overpayment. According to CMS, this standard, as well as the requirement to conduct a timely, good faith investigation in response to obtaining credible information of a potential overpayment, provide “bright line” standards that should assist providers in structuring their compliance programs to comply with the rule.²⁶

Significantly, CMS declined to attribute knowledge of an overpayment by the organization to only those situations where senior officials have confirmed the overpayment. Rather, CMS stated that “organizations are responsible for the activities of their employees and agents at all levels.”²⁷ Thus, should a lower level employee have knowledge of an overpayment, the 60-day clock would not necessarily wait until a senior official confirmed this knowledge.²⁸

E. Six-Year Lookback Period With No Minimum Materiality Threshold (81 Fed. Reg. at 7671-74)

The Final Rule adopted a six-year lookback period, which means “overpayments must be reported and returned only if a person identifies the overpayment within six years of the date the overpayment was received.”²⁹ The lookback period is specifically measured “back from the date the person identifies the overpayment.”³⁰ The six-year lookback period follows the Final Rule for Medicare Parts C and D and is a significant reduction from the ten-year lookback period that CMS included in the Proposed Rule. Although CMS contends ten years remains justifiable, it adopted a six-year lookback period after considering a number of factors and suggested alternatives.³¹

CMS initially proposed a ten-year lookback period because that is the “outer limit” of the [FCA] statute of limitations.³² However, CMS subsequently acknowledged that the FCA is strictly a fraud enforcement statute, whereas the 60-day rule would apply to many overpayments that are merely the product of errors or mistakes. Moreover, the FCA’s ten-year “outer limit” applies only in “extreme cases, where knowingly false or fraudulent claims have been actively concealed from discovery.”³³ The FCA’s six-year statute of limitations is more commonly used.

CMS also recognized that the proposed ten-year lookback period would be more burdensome than even the most stringent record retention requirements.³⁴ Hospital conditions of participation, for example, impose a five-year record retention requirement.³⁵ And

¹⁸ *Id.* at 7662.

¹⁹ *Id.* at 7661.

²⁰ *Id.* at 7662.

²¹ *Id.* at 7662.

²² *Id.* at 7662-63.

²³ *Id.* at 7665.

²⁴ *Id.*

²⁵ *Id.* at 7667.

²⁶ *Id.* at 7663.

²⁷ *Id.* at 7665.

²⁸ *Id.*

²⁹ *Id.* at 7654.

³⁰ *Id.* at 7671.

³¹ *Id.* at 7672.

³² *Id.* at 7671.

³³ *Id.* at 7672.

³⁴ *Id.* at 7671 – 72.

³⁵ *Id.* at 7671 (citing 42 CFR 482.24).

the standard record retention policies of many other providers is seven years.³⁶ As a matter of practicality, CMS acknowledged a ten-year record retention policy would increase the burden, costs, and complexity of investigating a potential overpayment.³⁷ CMS concluded that a six-year lookback period, on the other hand, would impose minimal, if any, additional burdens to existing record retention requirements.³⁸

CMS also considered but rejected comments seeking a shorter lookback period. For example, several commenters suggested that a one-year lookback period should apply, because that is the time allotted for providers to rebill a claim to correct an identified underpayment. CMS simply responded that the Final Rule concerns overpayments, thus, “underpayment issues are outside the scope of this rulemaking.”³⁹ Other commenters suggested the lookback period should be consistent with the three-year limitation on Recovery Audit Contractor (RAC) audits. CMS did not find this reasoning persuasive, but it did clarify that a RAC finding may serve as “credible information of a potential overpayment[.]”⁴⁰ Thus, although the RAC audit may be limited to three years, based on the RAC’s findings, the provider may still need to investigate whether they have received similar overpayments going back six years.⁴¹

CMS also explicitly declined to adopt a minimum materiality threshold for overpayments.⁴²

Importantly, the Final Rule expands the claims reopening regulation “to provide a reopening period that accommodates the 6-year lookback period.”⁴³ The addition made to that regulation, 42 C.F.R. § 405.980, explicitly allows providers to “request that a contractor reopen an initial determination for the purpose of reporting and returning an overpayment under § 401.305 of this chapter.”⁴⁴ CMS stated that this was an administrative accommodation for providers that is necessary to prevent obstacles and unintended loopholes to compliance with the Final Rule.⁴⁵

Under 42 C.F.R. § 405.980(b), a claim determination is generally not subject to reopening more than four years after the date the determination was made, unless there was a clerical error or the determination “was procured by fraud or similar fault.” The addition of 42 C.F.R. § 405.980(c)(4) arguably extends the reopening period for purposes of addressing overpaid claims. However, CMS did not make a parallel change to extend the reopening period to address underpayments. Inexplicably, CMS did not make a similar addition to the reopening regulation that applies to Medicare cost reports, 42 C.F.R. § 405.1885, under which a cost report is generally not subject to reopening more than three years after the date the determination was made, unless the determination “was procured by fraud or similar fault.”

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* at 7672.

³⁹ *Id.* at 7658.

⁴⁰ *Id.* at 7672.

⁴¹ *Id.*

⁴² *Id.* at 7677-78 (CMS believes that adopting such a “standard would be susceptible to abuse, especially in the context of claims-based overpayments.”).

⁴³ *Id.* at 7671.

⁴⁴ 42 C.F.R. § 405.980(c)(4).

⁴⁵ *Id.*

F. Process for Reporting and Returning an Overpayment (81 Fed. Reg. at 7674-80)

In the Final Rule, CMS endorsed the use of existing processes for reporting and returning overpayments, while noting the possibility that new processes could be developed in the future. In the Proposed Rule, CMS did not address the extent to which, if at all, use of such existing processes would be acceptable. Importantly, the Final Rule explicitly notes that providers may use claims adjustment, credit balance, or another appropriate process set forth by the applicable Medicare carrier, the OIG Self-Disclosure Protocol (SDP) or the SRDP.⁴⁶

In a welcome change from the Proposed Rule, the Final Rule does not include a list of mandatory data elements to be reported, noting that these can vary depending on the situation and method used. For example, providers may not always be required to report how the overpayment was discovered and provide a corrective action plan.⁴⁷ Nonetheless, providers must comply with the requirements of the reporting method they use. For example, providers using the SDP or SRDP must use the reporting processes described in the respective protocol. In addition, when providers extrapolate the overpayment amount using statistical sampling (discussed below), the overpayment report must explain how the overpayment was calculated and explain the statistical sampling methodology.

Regardless of the refund process selected, the actual report and refund must be submitted within 60 days of the date the overpayment is identified. However, the deadline for returning the overpayment will be tolled if: (1) a provider requests an extended repayment schedule under 42 C.F.R. § 401.603, or (2) a provider makes a submission under the SDP or SRDP. If the provider requests an extended repayment schedule, the repayment deadline will be tolled so long as the provider complies with the terms of the extended repayment schedule or until the Medicare contractor rejects the request. For the SDP or SRDP, the deadline will be tolled for the entire period in which the provider is negotiating a settlement, beginning when OIG or CMS acknowledges receipt of a submission for SDP or SRDP. If a provider fails to reach a settlement with OIG or CMS, the provider will have “the balance of the 60-day time period remaining from identification to the suspension of that 60-day period” to make a full report and repayment of the overpayment.⁴⁸

The Final Rule recognizes that providers may quantify the amount of an overpayment using statistical sampling, extrapolation methodologies, and other methodologies as appropriate.⁴⁹ Proposed Rule commenters sought clarity about when to refund an overpayment identified during a probe sample. Should the provider issue a refund within 60 days after the probe sample overpayment is identified or can the provider wait until the overpayment for the claims universe is quantified through extrapolation, even if that means that the pro-

⁴⁶ 42 C.F.R. § 401.305(e)(1).

⁴⁷ 81 Fed. Reg. at 7676 (“While we believe that the facts about how the overpayment was discovered and corrective action plans are relevant information relating to the reason for the overpayment, and thus within the purview of the statute, we also recognize that the additional burden of providing this information may not be necessary in all overpayments.”).

⁴⁸ See 42 C.F.R. § 401.305(b)(2)(i) – (ii).

⁴⁹ 81 Fed. Reg. at 7663 – 64.

vider held the identified probe sample overpayment for more than 60 days? Under these circumstances, CMS stated that the provider should not return the subset of claims identified as overpayments in a probe sample, but wait until the full amount of the overpayment is identified through extrapolation.⁵⁰ CMS opined that, in most cases, extrapolation and identification of the full overpayment can be done in a timely manner.

G. Effect of Overpayment Refunds on Appeal Rights (81 Fed. Reg. at 7667 – 68)

The intersection of appeal rights and the overpayment refund process has been another source of confusion because a favorable appeal decision generally means that the provider is entitled to the payment and, therefore, there was no overpayment. If a provider is not sure whether it has an overpayment, it may want to have that clarified through the appeal process. Thus, the Proposed Rule included comments seeking to confirm that providers have appeal rights to self-identified overpayments. CMS rejected these comments, stating that it would not expand the list of actions that constitute an initial determination providing an appeal right. The Final Rule states that it would be inconsistent with the intent of the statute and regulations for persons to return self-identified overpayments and then appeal those overpayments as a means to circumvent (1) the duty for timely investigation of all related potential overpayments, or (2) the deadline for reporting and returning of identified overpayments.

However, CMS acknowledged that a provider *does* have the right to appeal a revised contractor determination, which would be issued when an overpayment is returned by adjusting specific claims.⁵¹ Thus, CMS acknowledged that providers have appeal rights to overpayment refunds, but only where the overpaid claims are adjusted individually and a new determination is issued.

But what about overpayment amounts based on sampling and extrapolation, which typically do not result in the issuance of a revised claims determination because the overpayment is returned in a lump sum? Commenters asked CMS to clarify that providers retain appeal right for claims refunded based on statistical sampling.⁵² CMS refused to do so, noting that existing processes provide no appeal right for overpayments that do not result in a revised initial determination for overpaid claims, thereby denying providers appeal rights for most claims where statistical sampling is employed.

Proposed Rule commenters also expressed the view that the obligation to report and return an overpayment identified by a Medicare contractor and appealed by the provider should wait until the first two levels of the appeal process is completed. In the preamble to the Final Rule, CMS distinguishes between the appeals process for contractor overpayment determinations and the provider's separate responsibility to investigate credible information in good faith and in a timely manner. The 60-day report and return statute addresses the latter responsibility rather than the former process. CMS goes on to note that Medicare contractor overpayment determinations are "always a credible source of information

for other potential overpayments," and that such a determination may serve as the basis for a Medicare contractor-identified overpayment for one time period and could also serve as a basis for an overpayment for an additional time period that is (1) not covered by the contractor audit, (2) not administratively final, and (3) within the lookback period.⁵³ Under these circumstances, if the provider appeals the contractor-identified overpayment, the provider may reasonably take the position that it is premature to investigate the nearly identical conduct in an additional time period until the appeal has been completed.⁵⁴

The Final Rule acknowledged provider concerns that refunded overpayments might nevertheless be the subject of a recovery audit and recommended that providers retain their audit and refund documentation in the event that a Medicare contractor or the OIG audits claims that the provider believes have already been refunded. CMS will not recover an overpayment twice.⁵⁵

H. Overpayments Arising From Violations of the Anti-Kickback Statute (81 Fed. Reg. at 7666)

Both the Proposed Rule and Final Rule discussed extensively overpayments associated with a violation of the Anti-Kickback statute (AKS). Specifically, because compliance with the AKS is a condition of payment, violations of the AKS may expose providers to FCA liability. CMS considered how providers are often not a party to or are wholly unaware of arrangements between third parties that cause the providers to submit claims that are the subject of a kickback.

Moreover, even if a provider becomes aware of a potential third-party payment arrangement, it would generally not be able to evaluate whether the payment was an illegal kickback or whether one or both parties had the requisite intent to violate the AKS. As such, CMS stated that providers, not a party to a kickback arrangement, are unlikely to have "identified" the overpayment that has resulted therefrom and thus, have no duty to report or repay it. CMS did however, indicate that where the provider did have sufficient knowledge of the arrangement to have identified the resulting overpayment, then reporting would be required. While repayment enforcement would typically focus on the parties involved in the scheme, CMS did not rule out extraordinary circumstances where the innocent provider that identifies the kickback, may have to repay the overpayment.⁵⁶

I. Cost Report Issues (81 Fed. Reg. at 7668-71)

Overpayments addressed in Medicare costs reports must be reported and refunded the later of 60 days af-

⁵³ *Id.* at 7667.

⁵⁴ *Id.*

⁵⁵ *Id.* at 7666 – 67.

⁵⁶ In response to a question concerning hospitalists who assign their Medicare payments, CMS stated that "an entity to which a provider or supplier has reassigned Medicare payments has a duty to determine whether it has received overpayments associated with that provider or supplier." 81 Fed. Reg. at 7665. However, CMS refused to rule out the possibility that an individual who has reassigned Medicare payments could be responsible for the overpayment, stating that such responsibility will depend on factual inquiry into the individual's knowledge of the circumstances leading to the overpayment. *Id.*

⁵⁰ *Id.* at 7663 – 64.

⁵¹ *Id.* at 7668.

⁵² *Id.*

ter identification or the date the cost report is due (generally five months after the end of the cost reporting period).⁵⁷ ACA § 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 Final Rule limits “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.⁵⁸

Accordingly, the Final Rule defines applicable reconciliation as occurring when a cost report is filed, except where the provider either receives updated supplemental security income 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, which presumably occurs with the issuance of the Medicare Notice of Program Reimbursement.⁵⁹ Thus, CMS rejects the view that cost report overpayments generally need not be reported until the cost report is finally settled, despite the “applicable reconciliation” language.⁶⁰

In addition, the Final Rule 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.⁶¹ For example, an overpayment related to graduate medical education 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.⁶² By contrast, issues involving upcoding must be reported and returned within 60 days of identification, because upcoded claims are not presented for payment in the Medicare cost report.⁶³

J. Retroactivity (81 Fed. Reg. at 7673-74)

The six-year lookback period, like the rest of the Final Rule, is “not retroactive.”⁶⁴ If a provider investigated, reported, and returned an overpayment before the effective date of the Final Rule, the provider may rely on its “good-faith and reasonable interpretation” of the statutory requirements, 42 U.S.C. § 1320a-7k(d).⁶⁵

⁵⁷ See *id.* at 7654 (“This final rule states that a provider or supplier must (1) report and return an overpayment . . . by the later of 60 days after the overpayment was identified or the date the corresponding cost report is due. . . .”).

⁵⁸ *Id.* at 7669.

⁵⁹ See 42 C.F.R. § 401.305(c)(2)(i) and (ii).

⁶⁰ See 81 Fed. Reg. at 7669 (“Commenters recommended ‘applicable reconciliation’ in the context of cost reporting occur upon the final settlement of a provider’s cost report . . . We appreciate the comments on this issue. However, we are finalizing the definition of applicable reconciliation as proposed.”).

⁶¹ See *id.* at 7657 (“While some payments are cost-based estimated payments . . . many payments are not, such as claims-based payments under fee-for-service or prospective payment systems.”); see also *id.* at 7670 (“An overpayment as a result of an outlier reconciliation would be identified . . . as part of the cost report settlement process . . . However, for claims, if the provider identifies an inaccurate outlier claim payment, the provider must follow the overpayment payment reporting process for claims, as noted in this final rule.”).

⁶² See *id.*

⁶³ See *id.*

⁶⁴ *Id.* at 7673.

⁶⁵ *Id.* at 7674.

The provider need not conduct another investigation to cover the six-year lookback period or meet other requirements of the final rule.

With regard to self-referral overpayments CMS observes that Office of Management and Budget (OMB) has only approved the collection of financial information for a four-year lookback period under the SRDP. Therefore, until notification of changes to the SRDP lookback period, providers may choose to voluntarily submit financial information from the fifth and sixth years or to discharge their report and return obligation for those years through means other than the SRDP.⁶⁶ Thus, failing to voluntarily disclose the additional claims data through the SRDP process would prompt an obligation to report and repay in full within 60 days for the two additional years. Lastly, CMS notes that any self-referral overpayments reported in accordance with the SRDP prior to March 14, 2016, is only subject to the then-existing four-year SRDP lookback period even if the claims are compromised and settled after that date.⁶⁷

III. Takeaways for Providers Under the Final Rule

Here is a set of takeaways for providers to keep in mind as they implement the Final Rule:

1. The Final Rule’s definition of “identification,” which requires the exercise of “reasonable diligence” both reactively and proactively, places significant emphasis on the strength of a provider’s internal controls and compliance program, and the ability to move fast. The preamble to the Final Rule includes examples of proactive compliance activities, such as reviewing the OIG’s annual work plan.⁶⁸

2. Even with the recognition by CMS that a reasonable investigation could take several months, given the serious penalties associated with the 60-day report and return statute, providers likely will err on the side of overpayment disclosure, even in cases where additional time and consideration might lead a provider to conclude that, in fact, no overpayment had occurred.

3. In light of CMS’s statement concerning proactive compliance and corporate responsibility, every provider should strive to create an environment where information regarding potential overpayments is timely reported by lower level employees in accordance with an effective compliance plan.

4. With regard to whether underpayments can be used to reduce identified overpayments, CMS simply responded that the Final Rule concerns overpayments, thus, “underpayment issues are outside the scope of this rulemaking.”⁶⁹ Thus, providers will need to continue to address underpayments through the appropriate processes, rather than through offset of overpayments.

⁶⁶ *Id.* at 7673.

⁶⁷ *Id.*

⁶⁸ *Id.* at 7667 (CMS does not rule out that general government notices might trigger a provider’s duty to inquire about potential overpayments, and thus, encourages providers “to take advantage of publicly available information, such as the OIG’s annual work plan and CMS notices, to inform their planning of proactive compliance monitoring activities and retroactive reviews.”).

⁶⁹ *Id.* at 7658.

5. CMS has yet to initiate rulemaking with regard to the application of the 60-day report and return statute to Medicaid overpayments. So, while there is no federal authority beyond the statute, it is important to check state law for authorities addressing Medicaid overpayment requirements while also drawing from CMS's Medicare overpayment guidance by analogy where appropriate.

6. The Final Rule makes clear that providers are responsible for reporting and returning overpayments, even where the provider was not responsible for the overpayment.

7. We have long noted that providers need to operationalize the overpayment investigation and refund process and document their diligence. The Final Rule includes significant additional guidance that providers will need to keep in mind as they review their compliance programs, which will almost assuredly result in increased operational costs for providers.

8. The regulations added by the Final Rule do not even fill one page; the other 29 pages of the Final Rule contain extensive explanation of not only the overpayment refund process but also how it may apply in several substantive circumstances. Thus, the preamble of the Final Rule references many thorny substantive overpayment issues, such as evaluation and management coding. Although the Final Rule may not provide conclusive guidance on these issues, it will be important to consult the preambulatory language when these issues arise, if for no other reason than to make sure that you are aware of the agency's thinking on them.

8. The six-month period for investigation provides some breathing room for providers that are exercising reasonable diligence in investigating potential overpayments. As this is an outside limit (except under extraordinary circumstances), providers should conduct all overpayment activities promptly, comprehensively, and diligently, while properly documenting them.

IV. Conclusion

On its face, the 60-day report and return statute is simple: providers must return identified Medicare overpayments within 60 days. Certainly, we can all envision circumstances where doing so is straight-forward—a provider finds out it has been paid twice for the same service and submits the refund. But as providers realized shortly after enactment, applying the statute to the myriad of Medicare payments is anything but simple. For that reason, providers were not surprised that it took CMS almost two years to issue the Proposed Rule and another four years to publish the Final Rule.

We readily acknowledge that the Final Rule reflects a significant amount of thought—CMS seemed to be trying to make the pieces fit together, apparently in coordination with both the OIG and Department of Justice. But in doing so, the agency left many essential terms vague, such as “reasonable diligence,” “proactive compliance,” and “credible information.” This was apparently done to allow an organic application of this Final Rule to evolve over time, informed by experience with real-life circumstances, thereby giving providers proper advanced notice of how these terms will be applied.

When considering enforcement, we call upon the agency and courts to be flexible, so as to assure that providers are given fair notice of how these vague terms will be applied to the various overpayment scenarios they face on a daily basis before they are subject not only to refunding overpayments with a six-year look-back, but also potentially CMPs, federal program exclusion, and litigation costs and liability under the FCA.

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