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ALERT

Health Care

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The 60-Day Rule: CMS Issues Final Rule on Reporting & Return of Overpayments

On February 12, 2016, the Centers for Medicare & Medicaid Services ("CMS") published in the *Federal Register* a Final Rule regarding the so-called "60-day rule": the obligation of providers and suppliers to report and return Medicare overpayments within 60 days of their "identification." A provider or supplier who retains overpayments beyond that 60-day period risks liability under the reverse false claims provisions of the False Claims Act.[1]

Highlights

- The Final Rule provides much-needed clarity with respect to the ability of a provider or supplier to investigate an overpayment claim without starting the 60-day clock.
- Nonetheless, providers and suppliers must act promptly to investigate any credible information of a potential overpayment.
- CMS will institute a six-year "look back" period for overpayments (rather than ten, as originally proposed).
- Providers and suppliers must report and return overpayments even if they did not cause the overpayment.

Major Elements of the Final Rule

Definition of "Identification." The Final Rule defines "identification" as when a person "has, or should have through the exercise of reasonable diligence," determined and quantified the amount of the overpayment. This definition was intended to resolve ambiguity in the Proposed Rule as to whether time spent quantifying the amount of the overpayment would toll the 60-day clock or eat into the 60 days. In making this modification to the Proposed Rule, CMS agreed with commenters who asserted "that the calculation necessarily must happen before the overpayment can be reported and returned." Significantly, other regulators—including the New York State Office of the Medicaid Inspector General—had previously distinguished between identification and quantification in their application of the rule.

Providers and suppliers still must exercise "reasonable diligence," which requires (1) implementing proactive compliance activities to monitor for the receipt of overpayments, and (2) undertaking investigations "in a timely manner" in response to obtaining "credible information" of a potential overpayment. CMS stated in the preamble that it considers a "timely" investigation to be "at most 6 months from receipt of the credible information, except in extraordinary circumstances." Reflecting the agency's experience, and providing a yardstick of sorts, CMS specifically identifies Stark Law investigations that are disclosed pursuant to the CMS Voluntary Self-Referral Disclosure Protocol ("SRDP") as those that could involve these extraordinary circumstances.

Failure to undertake "reasonable diligence" could start the clock as of the day on which the provider or supplier "received credible information of a potential overpayment." *Thus, while the Final Rule does provide some confirmation that a provider or supplier may investigate without starting the 60-day clock, providers and suppliers should assure that they investigate any credible information of a potential overpayment promptly.* As a result,

[1] Section 6402 of the Patient Protection and Affordable Care Act (the "ACA"), subsequently codified in 42 U.S.C. § 1320a-7k

providers and suppliers should ensure that they have a robust compliance program in place that can effectuate this reasonable diligence standard.

Six-Year Look-Back Period. CMS has retreated from its proposed ten-year look-back period, now requiring the reporting and return of any overpayment identified within six years from the date it was received. CMS noted that this aligns with various existing federal and state document retention requirements.

Refund Process. The Proposed Rule suggested that providers and suppliers must use the voluntary refund process when reporting and returning overpayments. CMS has now clarified that providers and suppliers may use the claims adjustment, credit balance, self-reported refund process, or other appropriate process to report and return overpayments. However, CMS reserved the right to modify or create new processes in the future. Regardless of the process used, the refund should include an explanation of the statistical sampling methodology used if an overpayment was calculated by extrapolation.

Third-Party Violations of the Anti-Kickback Statute. CMS affirmed its position originally stated in the preamble to the Proposed Rule that compliance with the Anti-Kickback Statute is a condition of payment and, therefore, a provider or supplier could have a repayment obligation arising from a third party's violation of that law (*e.g.*, a hospital could be obligated to refund payments for a surgery performed by a physician who has received a kickback from a device manufacturer to implant the manufacturer's device). However, CMS reiterated without change the commentary from the Proposed Rule that provides that CMS would "suspend the repayment obligation until the government has resolved the kickback matter," and that its "expectation is that only the parties to the kickback scheme would be required to repay the overpayment . . . except in the most extraordinary circumstances."

Overpayments Not Caused by Provider or Supplier. In the Final Rule, CMS noted that a number of commenters requested that overpayments not caused by the provider or supplier or that otherwise were outside of the provider's or supplier's control should be excluded from the proposed definition of overpayment (*e.g.*, a CMS system error classifying a Medicare beneficiary as fee-for-service when the beneficiary was enrolled in a Medicare Advantage Plan; or if the Medicare contractor makes a duplicate payment). CMS declined to exclude these from the definition of "overpayment," thereby subjecting them to the 60-day requirement. Practically speaking, this will require providers and suppliers to assure that they have proactive compliance activities to detect errors made by other entities, including CMS itself.

Tolling in the Context of SRDP and SDP. CMS confirmed that a provider or supplier's use of the SRDP or the OIG Self-Disclosure Protocol ("SDP") will toll the deadline for returning an overpayment. However, it declined to extend the tolling to self-disclosures made to other government agencies, such as the Department of Justice.

Context of Final Rule

This Final Rule applies to Medicare Parts A and B. A separate Final Rule published in May 2014 applies to overpayments under Medicare Parts C and D. No Final Rule has been published that addresses Medicaid requirements; however, some states have developed their own guidance and requirements that may apply. Additionally, case law has emerged since the ACA first implemented its 60-day overpayment provision. Specifically, in *Kane v. Healthfirst, Inc. et al.*, Case No. 1:11-02325 (S.D.N.Y. 2015), the United States intervened in a False Claims Act qui tam lawsuit alleging violations of the ACA provision related to overpayments from the New York State Medicaid program ("NY Medicaid"). In that case, a health system, in response to questions from state auditors, identified a software glitch that resulted in submission of improper claims to NY Medicaid; the health system subsequently took over a year to quantify these improper claims and an additional two years to submit all refunds for the improper claims to NY Medicaid. The court concluded that the 60-day clock began to run when the provider was on notice of the potential overpayment. Providers and suppliers facing potential overpayments now can draw not only on the *Healthfirst* case, and its particular facts, but also on the extensive commentary provided by CMS in the preamble to the Final Rule when determining their compliance with the 60-day requirement.

If you have any questions about this Final Rule, please contact your usual Ropes & Gray attorney.