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CMS Proposes Amendment to 60-Day Overpayment Rule that Would Remove "Reasonable Diligence" Standard and Replace with False Claims Act's "Actual Knowledge" Standard

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On December 27, 2022, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule that would, among other things, amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an "identified overpayment" and the requirement to report and return overpayments within 60 days (the 60-day Rule).

If finalized, the rule change would revise the meaning of "identification" in 42 C.F.R. §§ 401.305(a)(2), 422.326(c), and 423.360(c) of the Affordable Care Act (ACA) to remove the "reasonable diligence" standard and replace it with the False Claims Act's (FCA's) "knowing" standard. Under the proposed rule, providers, suppliers, Medicare Advantage Organizations (MAOs), and Part D sponsors will be deemed to have identified an overpayment if they have "actual knowledge of the existence of the overpayment or act in reckless disregard or deliberate ignorance of the overpayment." CMS is seeking comments on or before February 13, 2023.

The Current 60-Day Rule

Under the current 60-day Rule, an overpayment must be reported and returned within 60 days of identification to the Secretary, the state, an intermediary, a carrier, or a contractor, as appropriate, and must also notify that entity in writing of the reason for the overpayment. The current rule defines identification to include when the provider or supplier determined *or* should have determined *through the exercise of reasonable diligence* that they have received and retained an overpayment. In its commentary on the final regulations concerning the 60-day Rule, CMS described "reasonable diligence" to include both "proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments" and "investigations conducted in good faith and in a timely manner by qualified individuals in response to the receipt of credible information of a potential overpayment."[1]

Under the current rule, a provider or supplier has six months to conduct a good-faith investigation once it receives "credible information" about a potential overpayment, except in extraordinary circumstances.[2] CMS has emphasized that extraordinary circumstances "may include unusually complex investigations that the provider or supplier reasonably anticipates will require more than six months to investigate, such as physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP)."[3]

Litigation Influencing the Proposed Rule

The proposed rule is influenced by the outcome of the litigation in *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173 (D.D.C. 2018), *rev'd in part on other grounds sub nom. UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140).

In *UnitedHealthcare Ins. Co. v. Azar*, the U.S District Court for the District of Columbia held, in pertinent part, that the "reasonable diligence" standard in the overpayment rule applicable to MAOs impermissibly created

FCA liability for "mere negligence," which conflicted with the FCA's knowledge standard. The district court thus vacated the rule as applicable to MAOs.

The Court of Appeals for the District of Columbia reversed the decision of the district court and reinstated the overpayment rule as applicable to MAOs. The U.S. Supreme Court denied cert. Notably, CMS did not appeal the district court's decision holding that CMS adoption of a negligence standard in the overpayment rule, as applicable to MAOs, violated the Administrative Procedures Act. Thus, the court's decision has led to scrutiny concerning whether providers and suppliers, MAOs, and Part D sponsors must engage in reasonable diligence to self-audit to identify overpayments.

Implications of the Proposed Rule

As proposed, the revised 60-day Rule only would require Medicare Parts A and B providers and suppliers, Part C MAOs, and Part D sponsors to report and return an overpayment if they have ***actual knowledge*** of the existence of an overpayment or ***act in reckless disregard*** or ***deliberate ignorance*** of an overpayment. Actual knowledge under the FCA is generally considered to mean that a person knows that the particular activity has occurred — they have received information in a way that made them believe it to be true.

The proposed change to the rule raises significant questions about the applicability of the knowing standard under the FCA, including whether the standard creates a duty to engage proactively in compliance activities to monitor for the receipt of overpayments. Because the knowing standard also includes deliberate ignorance and reckless disregard, there is presumably a duty to make inquiries to ensure the accuracy of the information received before determining whether there is an overpayment. The proposed rule raises further questions about whether the nuances of the 60-day Rule, as explored by CMS in the original preamble, would continue to apply to the amended definition.

For example, it is common for providers to obtain information about a potential overpayment quickly but require further investigation to determine the exact amount to report and return. As discussed, CMS previously indicated that it would consider an investigation that took up to six months to complete to identify the specific overpayment amount to be reasonable. CMS has not indicated whether this same approach would apply under the new standard. The knowing standard, without a defined reasonable diligence period, could lead to increased enforcement actions. However, if the knowing standard is adopted, then the failure to return and report overpayments within the 60-day timeframe may not give rise to liability under the FCA if a Medicare Part A or B provider, supplier, Part C MAO, or Part D sponsor can demonstrate a good-faith diligent effort to comply with the law so that their failure to timely report and return an overpayment would, at most, amount to mere negligence.

Those affected by this rule change should consider submitting written comments to CMS before the February 13, 2023, deadline. As entities prepare for potential changes to their compliance policies and approaches, they should also consider closely other potential obligations to report and return overpayments that may not be tied to the 60-day Rule.

For more information about this topic, please contact Alissa D. Fleming, Matthew W. Wolfe, or any member of Baker Donelson's Health Law team.

[1] 81 Fed. Reg. 7653, 7661.

[2] 81 Fed. Reg. 7653, 7662.

[3] Id.