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No More Reasonable Diligence? CMS Proposes to Change Standard for Identifying Medicare Overpayments to Align with False Claims Act

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On December 27, 2022, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule (Proposed Rule) which proposes certain policy and technical changes to Medicare regulations, including a notable change to the current standard under the "60-Day Rule" for identifying a Medicare overpayment. Specifically, CMS indicated that it is proposing to (i) "adopt by reference" the federal False Claims Act's (FCA) definitions of "knowing" and "knowingly" as governing when an overpayment is identified, and (ii) eliminate the "reasonable diligence" standard that has been in place, but subject to challenges, for a number of years.

The 60-Day Rule was established by the Affordable Care Act, and it requires a health care provider that receives an overpayment to report and return the overpayment by the later of (i) 60 days after the provider identifies the overpayment or (ii) the date any corresponding cost report is due. The failure to report and return an overpayment within the 60-Day Rule's time frame establishes liability under the FCA. This threat of a "reverse false claim" arising from a retained overpayment subjects providers to significant potential liability under the FCA, including treble damages and civil penalties. Accordingly, the 60-Day Rule poses a significant obligation for all providers who receive Medicare or Medicaid payments, and the issue of when an overpayment is "identified" is crucial to maintaining compliance. However, that term was not defined in the statute.

In 2014 (for Medicare Parts C and D) and 2016 (for Medicare Parts A and B), CMS issued rules and regulations which establish that a provider "identifies" an overpayment when the provider determines, or should have determined through the exercise of reasonable diligence, that the provider received an overpayment. The so-called "reasonable diligence standard" under the Parts C and D regulations was challenged and overturned by a federal court in 2018 on the basis that it impermissibly established FCA liability for negligence by agency rulemaking.

In this Proposed Rule, CMS accedes to the determination of that federal court, and proposes to amend its respective regulations to remove the "reasonable diligence" standard language. Instead, CMS proposes language which states that a provider "has identified an overpayment when the person knowingly receives or retains an overpayment" and which defines "knowingly" by reference

to the FCA. Under the FCA, “knowing” and “knowingly” are terms of art defined to mean that a person (i) has actual knowledge of information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.

The proposed change appears to be intended to reduce ongoing uncertainty regarding the standard for identifying overpayments and may also provide defendants in FCA actions brought under the 60-Day Rule additional flexibility to argue against there being scienter to substantiate alleged overpayment violations. That said, health care providers would be well-advised to continue engaging in diligent compliance efforts to monitor payments and detect potential overpayments to avoid potential claims and costly litigation.

CMS is accepting comments on the Proposed Rule through February 13, 2023.

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