Published on *The National Law Review* https://natlawreview.com

Back to the Drawing Board: CMS Proposes Changing the Overpayment Rule's "Identified" Definition

Article By:

Emily J. Cook

Tony Maida

Monica Wallace

In December 2022, the Center for Medicare and Medicaid Services (CMS) unexpectedly issued a proposed rule that would materially change the obligations of entities participating in the Medicare program to report and return overpayments of Medicare Part A and Part B funds. The proposed rule would revert to the definition of "identified" that CMS originally proposed in 2012 and removes the concept of quantification of the overpayment serving as the start of the 60-day clock.

IN DEPTH

Rather than allow Part A and Part B providers and suppliers time to conduct "reasonable diligence" before determining that an overpayment has occurred and to quantify the amount of the overpayment, as set forth in the current overpayment refund rule at 42 C.F.R. § 401.305, the new proposed rule would require that Part A and Part B overpayments be reported and returned within 60 days of the provider or supplier having actual knowledge, or being in reckless disregard or deliberate ignorance, of the existence of the overpayment. Under the current rule, providers and suppliers that become aware that a potential overpayment may have occurred are expected to investigate the existence of the overpayment and determine the amount before notifying the government and returning the overpaid amounts. Only after the quantification of the overpayment does the 60-day clock begin to run on returning the overpayment to the government.

The proposed rule would remove the following language at 42 C.F.R. § 401.305(a)(2):

- A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

This language would be replaced with the new proposed 42 C.F.R. § 401.305(a)(2):

- A person has identified an overpayment when the person knowingly receives or retains an overpayment. The term “knowingly” has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

“Knowingly” as defined at 31 U.S.C. 3729(b)(1)(A) means “that a person, with respect to information—(i) has actual knowledge of the 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.”

Even though this is the same proposed definition as in the original rulemaking, CMS does not address the inherent ambiguities and practical problems presented by the proposed definition. For example, the proposed rule does not explain how a provider or supplier would return an overpayment within 60 days if the existence of the overpayment is known but the amount of the overpayment remains unknown. It is not uncommon for it to take several months, if not more, for a provider or supplier to determine the amount of an overpayment. CMS recognized this fact in the preamble to the current rule, but is silent on this issue in the new proposed rule. CMS also does not explain what it means to be in “reckless disregard or deliberate ignorance” that the provider or supplier received or retained an overpayment.

The proposed change appears to be the result of litigation surrounding the Medicare Part C and D overpayment rule (*UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 191 (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 which a federal court determined that CMS’s incorporation of “reasonable diligence” to investigate an overpayment in the Part C and D rule was outside of the agency’s rulemaking authority under the overpayment statute. However, the cited case concerned whether CMS could impose obligations of Part C plans to conduct investigations into potential overpayments, and did not address limiting the time period necessary to quantify the amount of an overpayment to 60 days. It is possible that CMS intends for the proposed rule to be interpreted to incorporate the quantification of the overpayment amount into the knowledge requirement, but such an interpretation is not articulated in the preamble. As the proposed rule is currently drafted, providers and suppliers could be put in a position of incurring reverse False Claims Act liability risk for overpayments that are known to exist but cannot be quantified within 60 days. Providers and suppliers may also risk being accused of having constructive knowledge that an overpayment was received or retained without any guidance as to what that means.

The proposed rule was inserted into a regulatory package issued on December 14, 2022, to be published in the Federal Register on December 27, 2022. The package primarily addressed issues (such as overpayment refunds) that are relevant to Medicare Part D sponsors and Medicare Advantage contractors, but that would not typically be relevant to Part A and Part B entities. Public comments on the proposed rule are due by February 13, 2023. We will issue future publications on the proposed rule in 2023 and encourage stakeholders to seriously consider providing comments given the operational challenges and potentially significant liability created by the proposed rule.

National Law Review, Volume XII, Number 358