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CMS Proposes to Amend Overpayment Rule, Remove Potential Overpayment and False Claims Act Liability for Mere Negligence

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The Centers for Medicare and Medicaid Services ("CMS") has issued a proposed rule which would amend the existing regulations for reporting and returning identified overpayments (the "Proposed Rule"). Specifically, with respect to the meaning of "identification" of overpayment, CMS proposes to eliminate the "reasonable diligence" (or traditional negligence) standard and replace it with the False Claims Act's ("FCA's") standard of "knowing" and "knowingly" (*i.e.*, reckless disregard or deliberate ignorance of a potential overpayment).

Under the current Overpayment Rule, a person who has received an overpayment must report and return it within 60 days of discovery 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. As currently written, the Overpayment Rule holds that a person has identified an overpayment when they have determined, or should have determined *through the exercise of reasonable diligence*, that they have received an overpayment.

UnitedHealthcare Litigation

UnitedHealthcare challenged the current Overpayment Rule in litigation.[1] One of its main arguments was that incorporating a negligence standard through the definition of "identification", *i.e.*, requiring Medicare Advantage Organizations ("MAOs") to use "reasonable diligence" in identifying overpayments, conflicted with the knowledge standard in the FCA and improperly created liability for mere negligence. The district court agreed with UnitedHealthcare and vacated the Overpayment Rule for MAOs. CMS appealed but did not challenge the court's findings about the negligence standard. The D.C. Court of Appeals reversed and allowed the Overpayment Rule to stand, but did not change the district court's holding that the adoption of a new negligence standard in the Overpayment Rule

violated the APA. Thus, MAOs and all other persons and entities subject to the Overpayment Rule (such as healthcare providers) were left in doubt as to whether the Overpayment Rule continued to require them to engage in proactive, "reasonable diligence" to self-audit or otherwise identify potential overpayments, lest they risk liability under the Overpayment Rule and potentially the FCA.

The Proposed Rule

If finalized, the Overpayment Rule will be amended at 42 C.F.R. §§ 401.305(a)(2), 422.326(c) and 423.360(c) to remove references to "reasonable diligence" and replace them with language that gives the terms "knowing" and "knowingly" the same meaning given those terms in the FCA. Therefore, if the Proposed Rule is finalized, a provider, supplier, MAO, or Part D sponsor will have identified an overpayment only if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.

This proposed change to the Overpayment Rule would offer welcome relief to providers, suppliers, MAOs, and Part D sponsors as they would no longer be held to the subjective "reasonable diligence" standard when determining whether an overpayment has been identified. Rather, liability stemming from the identification of overpayments would only be triggered under the FCA's heightened standard of actual knowledge, reckless disregard, or deliberate ignorance. Providers, suppliers, MAOs, and Part D sponsors are able to submit comments on CMS' proposal, should monitor the final rule closely, and should begin to consider potential changes to organizational policies and procedures regarding the identification and resolution of overpayments accordingly.

FOOTNOTES

[1] See *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).

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