Court Nixes CMS's Negligence Standard for Applying False Claims Act Liability for Failure to Report and Return Overpayments

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In what has become widely known as the "60-day rule," the Affordable Care Act (ACA) requires that Medicare and Medicaid overpayments be reported and returned within the later of the date which is 60 days after the date on which the overpayment was "identified" or the date any corresponding cost report is due.[1] The wrongful retention of an overpayment may result in liability under the False Claims Act (FCA).[2]

Perhaps the most vexing issue under the 60-day rule is the meaning of "identified," a term that is not defined in the statute. What level of notice or knowledge of an overpayment starts the 60-day clock? Is actual knowledge of an overpayment required? If not, what degree of constructive knowledge is sufficient? Is it enough that a provider should have known about the overpayment, or could have known had it exercised greater diligence?

A recent decision by the U.S. District Court for the District of Columbia—*UnitedHealthCare Insurance Co. v. Alex M. Azar II*—establishes some provider-friendly case law on these questions.[3] To appreciate the significance of the *UnitedHealthCare* case, it is helpful to first review how the Centers for Medicare and Medicaid Services (CMS) has approached these issues.

CMS's Reasonable Diligence Standard

In a 2014 regulation, CMS addressed Medicare Part C and Part D overpayments to Medicare Advantage (MA) insurers and Part D plan sponsors, respectively.[4] A 2016 regulation issued by CMS covered Medicare Part A and Part B overpayments.[5] In both regulations, CMS adopted an expansive interpretation of "identified."

The 2014 rule—addressing overpayments to MA organizations—provided that: "The MA organization has identified an overpayment when the MA organization has determined, or *should have determined through the exercise of reasonable diligence*, that the MA organization has received an overpayment."[6] In the preamble to the 2014 rule, CMS defined "reasonable diligence" to mean "at a minimum … proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments."[7]

The 2016 regulation—concerning Medicare Part A and Part B overpayments—included similar language, stating:

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

1 42 U.S.C. § 1320a-7k(d).
2 31 U.S.C. § 3729(a)(1)(G).
3 *UnitedHealthCare Insurance Co. v. Alex M. Azar II*, Case No. 16-157, 2018 WL 4275991 (D.D.C. Sept. 7, 2018).
4 *See* 79 Fed. Reg. 29843 (May 23, 2014).
5 81 Fed. Reg. 7654 (Feb. 12, 2016). CMS has not yet issued a regulation concerning Medicaid overpayments.
6 42 C.F.R. §422.326(c) (emphasis added).
7 79 Fed. Reg. at 29923.

reasonable diligence and the person in fact received an overpayment.[8]

In the preamble to the 2016 rule, CMS elaborated that "reasonable diligence," requires both:

- "investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment," and
- "proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments."[9]

The 2014 and 2016 CMS regulations raised a key question: Does a "reasonable diligence" standard mean that the merely negligent failure to identify and return an overpayment triggers FCA liability, along with all the attendant consequences, including treble damages, draconian per-claim penalties, and the reputational damage that accompanies being labeled as a False Claims Act offender? That seemed to be CMS's intent.

UnitedHealthCare Case

The court in UnitedHealthCare was focused on the 2014 regulation concerning overpayments to MA organizations. UnitedHealthCare complained that the 2014 rule unlawfully imposed a negligence standard on MA insurers in connection with reporting and returning overpayments and that this was inconsistent with the standards of the False Claims Act, which imposes liability for false claims for payment that are "knowingly" submitted to the government. "Knowingly" is defined in the FCA to encompass "actual knowledge," "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information."

The court accepted these arguments and vacated the 2014 rule, holding that FCA liability requires actual knowledge, deliberate ignorance, or reckless disregard of the falsity of a claim (or, in context of failure to return an overpayment, what is known as a "reverse" claim).[10] The court further observed that "Congress clearly had no intention to turn the FCA, a law designed to punish and deter fraud, into a vehicle for either 'punish[ing] honest mistakes or incorrect claims submitted through mere negligence' or imposing 'a burdensome obligation' . . . rather than a 'limited duty to inquire.'"[11] The court concluded that the 2014 rule "extends far beyond the False Claims Act and, by extension, the Affordable Care Act. Not being Congress, CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation."

Implications of the UnitedHealthCare Case

The holding in *UnitedHealthCare* applies only to the 2014 rule concerning Medicare Part C overpayments, but the court's rationale applies equally to the 2016 rule concerning Medicare Part A and Part B overpayments.

This author has previously maintained that CMS's negligence standard is contrary to the False Claims Act and, indeed, that one could go further and reasonably argue that even the "reckless disregard" and "deliberate ignorance" standards should not be used to impose FCA liability in the context of a failure to report and return overpayments.[12] In that regard, the term "identified" suggests an elevated level of knowledge of an overpayment, beyond mere recklessness. How can one be deemed to have "identified" something of which they are not consciously aware? Furthermore, the applicable language in the FCA refers to "knowingly and *improperly* avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government."[13] Although "knowingly" is defined in the FCA to include not only "actual knowledge," but

8 42 C.F.R. § 401.305(a)(2).
9 81 Fed. Reg. at 7661 (emphasis added).
10 31 U.S.C. § 3729(b)(1)(A).
11 The court also vacated the 2014 rule on the basis that it violated a statutory requirement that CMS must pay MA insurers the "actuarial equivalence" between Medicare and MA payments and that the same methodology be used to determine payments under Medicare and MA plans. That aspect of the court's ruling is not addressed here.
12 *UnitedHealthCare*, 2018 WL 4275991, at * 13, quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274-75 (D.C. Cir. 2010) (quoting S. Rep. No. 99-345, at 6, 19 (1986)).
13 *See* Glenn P. Hendrix, *Self-Reporting & Refunding Medicare Overpayments (The "60-Day Rule*), paper presented at American Health Lawyers Association Long-Term Care & The Law conference, Feb. 22, 2017.

also “deliberate ignorance of the truth or falsity of the information” and “reckless disregard of the truth or falsity of the information,” Congress’s further inclusion of the words “*and improperly*” suggests that something more is required and that a higher knowledge standard – perhaps requiring willful conduct – should apply.

The court in *UnitedHealthCare* did not go that far, but it didn’t have to in order to address the particular issues before it. Thus, the issue of whether FCA liability for failure to comply with the 60-day rule requires a heightened standard of knowledge remains open.

Nevertheless, the court’s holding that failure to exercise “reasonable diligence” (*i.e.*, a negligence standard) cannot result in FCA liability is a welcome development for MA insurers and Medicare providers and suppliers.

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