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What UnitedHealth's loss at the D.C. Circuit Means for Medicare Advantage Plans and FCA Enforcement

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On Friday, August 13, a D.C. Circuit panel unanimously unwound UnitedHealth Group's (UnitedHealth) successful challenge to the Medicare Advantage Overpayment Rule, determining that the Centers for Medicare and Medicaid Services' (CMS) requirement that private insurers return identified overpayments for unsupported diagnoses within sixty days did not improperly hold insurers to a higher standard than the Government. *See UnitedHealthcare Ins. Co., et al. v. Becerra*, No. 1:16-cv-00157 (D.C. Cir. 2021).

Background: The 60-Day Repayment Requirement and the Final Rule

The final rule section titled "Reporting and Returning of Overpayments" (the "Overpayment Rule") has its roots in the Affordable Care Act (ACA), which requires that "any overpayment ... be reported and returned [within] 60 days after the date on which the overpayment was identified" and that failure to do so renders the insurer's initial, but faulty, claim for payment a False Claims Act (FCA) violation. *See* 42 U.S.C. § 1320a-7k(d). However, the ACA left several crucial terms undefined. Most notably, it did not define at which point an insurer was said to have "identified" an overpayment, thus triggering the sixty-day shot clock. To remedy this, after a notice and comment period, CMS issued the Overpayment Rule in 2014. *See* 79 Fed. Reg. 29,843 (May 23, 2014), codified at 42 C.F.R. § 423.360. Under the Rule, any diagnostic code that lacks supporting documentation in a patient's medical chart results in an "overpayment," and an overpayment is "identified" whenever a Medicare Advantage insurer determines, "or should have determined through the exercise of reasonable diligence," that it had submitted

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fraudulent or unsupported codes that resulted in overpayment. In a preamble to the final Overpayment Rule, CMS further defined "reasonable diligence" as requiring "at a minimum ... proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments," and indicated that failure to act with reasonable diligence could place a Medicare Advantage insurer at risk of FCA liability.

District Court Ruling

In 2018, a D.C. district court judge vacated the Overpayment Rule, determining that CMS had not provided a legitimate reason for its failure to ensure equivalent payments between Medicare and Medicare Advantage. *See UnitedHealthcare Ins. Co. et al. v. Azar et al.*, No. 1:16-cv-00157 (D.D.C. 2018). In short, the court adopted the defense argument that the Overpayment Rule imposed an unfair standard by requiring that insurers proactively identify incorrect codes submitted through the Medicare Advantage program when CMS did not engage in similar behavior for traditional Medicare claims. Imposing such requirements violated "actuarial equivalence" — a statutory requirement designed to ensure relative consistency between payments for healthcare under Medicare and Medicare Advantage plans. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).

The district court further determined that CMS improperly exposed Medicare Advantage insurers to liability under the FCA by punishing them for negligently failing to return overpayments. According to the court, the Rule's negligence standard ran afoul of the FCA's requirement that a person "knowingly" submit false claims for payment to the Government — the FCA defines a person's conduct as "knowing" if he, she, or it has actual knowledge of the information or acts in deliberate ignorance or with reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1).

This decision marked an important win for UnitedHealth, as well as other providers and insurers, who leveraged it in concurrent FCA litigation involving allegations that defendants violated the FCA by failing to return overpayments, albeit with mixed results. *Compare U.S. ex rel. Poehling v. UnitedHealth*, 2:16-cv-08697 (C.D. Cal. 2019) (declining to award summary judgment because it was not clear as a matter of law that UnitedHealth was required by regulation or contract to delete invalid diagnosis codes it knew were unsupported by medical records) *with U.S. ex rel. Ormsby v. Sutter Health*, 3:15-cv-01062 (N.D. Cal. 2020) (denying motion to dismiss and concluding that actuarial equivalence is not a defense to an FCA claim).

D.C. Circuit Overturns

But on appeal, the D.C. Circuit overruled the lower Court in *Azar* and determined that the Overpayment Rule does not violate the Medicare statute's requirement of actuarial equivalence. Looking to the text, structure, and logic of the Rule, the court reasoned that "[t]he actuarial-equivalence requirement and the overpayment-refund obligation apply to different actors, target distinct issues arising at different times, and work at different levels of generality."

Though CMS did not challenge the district court's holding regarding the Rule's negligence standard on appeal, UnitedHealth argued that the Overpayment Rule requires insurers to audit all data they submit to CMS in light of the risk of liability under the FCA, while traditional Medicare data goes unaudited despite being littered with unsupported codes, thus causing CMS to underpay Medicare Advantage insurers. The D.C.

Circuit found this argument unconvincing, explaining that **the Overpayment Rule does not obligate insurers to audit their reported data, and insurers need only refund within sixty days payments insurers *know* lack support in beneficiaries' records.** The court highlighted the ACA's specific provision for FCA liability for insurers who fail to report and return overpayments within sixty days of their discovery, and emphasized that actuarial equivalence is not a valid defense against the repayment obligation, despite insurers' recent use of the defense against FCA allegations.

Further, the court determined that the Overpayment Rule does not violate the Medicare statute's requirement that CMS compute and publish the "average risk factor" for traditional Medicare beneficiaries on a county-by-county basis "using the same methodology as is expected to be applied in making payments" to Medicare Advantage insurers. Instead, CMS is only required to "use the same risk-adjustment model that it already uses to set monthly payments to Medicare Advantage insurers."

Finally, the D.C. Circuit reasoned that the Overpayment Rule was not arbitrary and capricious in violation of the Administrative Procedure Act despite UnitedHealth's claim of an "unexplained inconsistency" between the Overpayment Rule and another error-correction mechanism to which Medicare Advantage insurers are subject, known as Risk Adjustment Data Validation (RADV) audits. In conducting RADV audits, CMS retrospectively spot-checks insurer submissions to certify the accuracy of diagnosis codes and other data going back several years and requires Medicare Advantage insurers to return to CMS any payments based on a contract-level degree of error recorded in the audited sample. Put differently, UnitedHealth contended that CMS obligating repayment under the Overpayment Rule without requiring a similar RADV audit adjustment was improper. But because CMS implemented the RADV audit adjustment in response to actuarial equivalence concerns, and "the Overpayment Rule does not violate, or even implicate, actuarial equivalence," the D.C. Circuit determined that it was reasonable for CMS not to apply the adjustment or a similar correction in the context of returning overpayments.

What does the ruling mean to industry?

Despite CMS's declining to appeal the District Court's conclusion that the Final Rule's negligence standard was inconsistent with the FCA's scienter requirement, this decision and its termination of the actuarially equivalent defense is a major win for the U.S. Department of Justice (DOJ) and *qui tam* whistleblowers who have brought (or are looking to bring) cases grounded on a provider's or Medicare Advantage insurer's failure to report and return overpayments based on unsupported diagnoses. This is particularly true in the common "one-way audit" line of cases, where relators and the Government may prevail against a motion to dismiss by showing that the defendants knowingly failed to return overpayments or were reckless in failing to identify such overpayments. Indeed, the day this ruling issued, the Government and FCA defendants embroiled in major litigation on this same theory filed a joint stipulation indicating that they are presently working towards a settlement.

While DOJ has already identified Medicare Advantage as an area for increased enforcement – including back in December when DOJ's Michael Granston singled out Medicare Advantage fraud as an "important priority," particularly in situations where providers and plans "manipulate[] the risk adjustment process by

submitting unsupported diagnosis codes to make their patients appear sicker than they actually were" – and, as recently as last month, intervened in six complaints alleging members of the Kaiser Permanente consortium violated the FCA by submitting inaccurate diagnosis codes, this decision will likely spur even more Government and *qui tam* whistleblower actions. Accordingly, it is more important than ever for those participating in Medicare Advantage to be diligent in returning any overpayments they identify, and while the Overpayment Rule does not require that insurers audit their reported data, audits or reviews should nevertheless be structured in ways so that they cannot be accused of being reckless in not identifying such overpayments.