#### **ALERT** - Health Care

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# D.C. Circuit Overturns 2018 D.D.C. Decision Invalidating Medicare Advantage Overpayment Rule: Changed Compliance and Legal Landscape for Medicare Advantage

On August 13, 2021, the U.S. Court of Appeals for the D.C. Circuit issued a strongly worded, unanimous decision overturning a 2018 District Court decision striking down a 2014 rule, codified at 42 C.F.R. § 422.326, relating to the refunding of overpayments under the Medicare Advantage program (the "Overpayment Rule" or the "Rule"). Issued by the Centers for Medicare and Medicaid Services (CMS), the Overpayment Rule requires Medicare Advantage Organizations (MAOs) to refund payments received in connection with

Attorneys
Stephanie A. Webster
Devin Cohen
Stefan P. Schropp
Will Spelder

diagnostic codes unsupported by sufficient clinical documentation within 60 days of identifying such overpayments.<sup>2</sup> The Rule provides that an insurer has "identified" an overpayment when it has discovered or should have discovered an unsupported diagnosis that has been submitted to CMS for payment.<sup>3</sup> UnitedHealthcare Insurance Company and its subsidiaries/affiliates (collectively, "United") brought a challenge to the Rule in 2016, arguing that it violated the statutory mandate of actuarial equivalence and established a mere negligence standard for False Claims Act liability, as opposed to the standard requiring knowledge of falsity or reckless disregard towards the truth or falsity of reported information.<sup>4</sup> At the time it brought this challenge, United was defending a *qui tam* suit alleging False Claims Act violations of related regulations regarding the validity of submitted diagnostic codes.<sup>5</sup>

Though the appellate court struck down the lower court's decision vacating in its entirety the Overpayment Rule, CMS did not challenge, and, thus, the Court did not address, the question of whether CMS may subject MAOs to a different, negligence liability standard under the False Claims Act. Instead, the Court decided that the actuarial equivalence standard did not apply to the Overpayment Rule and, thus, could not be the basis for striking the Rule down. This alert reviews each decision in turn and concludes by analyzing what the appellate decision could mean for MAOs and their industry partners.

#### The Original District Court Decision in 2018

In 2016, a group of United's affiliated MAOs brought suit against CMS to challenge the Overpayment Rule, primarily asserting that it violated the Medicare statute's actuarial-equivalence requirement.<sup>6</sup> Actuarial equivalence refers to the statute's requirement that CMS adjust payment amounts to an MAO based on risk factors "so as to ensure actuarial equivalence" between the population of beneficiaries receiving benefits via traditional Medicare and that of beneficiaries receiving benefits via Medicare Advantage.<sup>7</sup> CMS establishes benchmarks to compensate MAOs based largely upon the historical claims data and payments made under traditional Medicare, subject to audit and adjustment. The actuarial-equivalence requirement is meant to ensure that CMS pays to a Medicare Advantage insurer the same amount it would pay if all of that insurer's Medicare Advantage beneficiaries were instead enrolled in traditional Medicare.<sup>8</sup>

United argued that the Overpayment Rule violated the principle of actuarial equivalence by requiring MAOs to refund payments related to unsupported diagnoses but did not require the base data from traditional Medicare beneficiaries to undergo the same monitoring or auditing scrutiny. This uneven verification standard, United argued, results in systematic underpayment to MAOs and violates the actuarial-equivalence requirement. If CMS receives refunds for Medicare Advantage overpayments but not for traditional Medicare overpayments, it pays less for Medicare Advantage, thereby violating actuarial equivalence, assuming the rest of the model functions as intended and calculates actuarially equivalent risk scores in the initial benchmark payments.

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The District Court agreed and vacated the Overpayment Rule, reasoning that "while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed." This, the Court held, made achieving actuarial equivalence impossible. 12

In addition, the District Court determined that the Rule's creation of what amounted to a negligence standard imposed liability beyond that provided for by statute under the False Claims Act. <sup>13</sup> While the False Claims Act imposes liability for false claims "knowingly" submitted to the government, the Overpayment Rule purported to impose False Claims Act liability when an MAO submitted a payment it *should have* known was false, even if it did not have actual knowledge of its falsity. <sup>14</sup> This, the Court ruled, was an improper exercise of legislative authority by CMS. <sup>15</sup>

The Court's decision initially came as a relief to MAOs and their industry partners and, as it conceded at oral argument, the government stopped "attempting to enforce the Overpayment Rule" pending appellate resolution. As a result, MAOs were able to operate under the assumption that the False Claims Act (at least for the moment) did not necessitate supplemental investments in compliance and auditing mechanisms by MAOs to mitigate risks of miscoded records, first-tier, downstream, and related entities ("FDRs") contractual amendments to pass through compliance obligations, or enhanced third-party auditing/coding engagements.

#### The D.C. Circuit Decision Overturning the 2018 Lower Court Decision

CMS appealed a number of aspects of the 2018 decision, and on August 13, 2021, the D.C. Circuit reversed the lower court's vacatur of the Overpayment Rule. The appellate court held that the Medicare statute's actuarial-equivalence requirement (contained in 42 U.S.C. § 1395w-23(a)(1)(C)(i)) did not apply to the Rule, which implemented a separate statutory provision (42 U.S.C. § 1320a-7k(d)). passed as part of the Affordable Care Act and required MAOs to refund overpayments. Further, the Court held, even if the actuarial-equivalence requirement did apply to the Rule, United failed to show that the Overpayment Rule would violate its underlying statistical requirement. Because CMS did not challenge the District Court's ruling on the negligence standard, the appellate court declined to address the issue.

First, the Court reasoned that the actuarial-equivalence statutory provision (42 U.S.C. § 1395w-23(a)(1)(C)(i)) nowhere referenced either the statutory provision governing refunds of overpayments (42 U.S.C. § 1320a-7k(d)) or the rule implementing that provision (42 C.F.R. § 422.326). Without any clear intent from Congress that the actuarial-equivalence standard applied to the Overpayment Rule, the Court concluded that there was no basis to assume Congress so intended, especially when the Overpayment Rule and the requirement "apply to different actors, target distinct issues arising at different times, and work at different levels of generality." The actuarial equivalence mandate directs CMS, not MAOs, in how to perform its risk adjustment modeling and focuses on the initial benchmark payments rather than the refunds that inherently come later. Although the initial benchmark payments made to MAOs need to be set as if the beneficiary pools were actuarially equivalent to the traditional Medicare population, there is nothing in the statute to prohibit CMS from requiring insurers to subsequently refund individual, known overpayments. The Court also noted that United had never challenged the propriety of the initial benchmark payments or the data on which they rely and, thus, could not now attempt to make such a challenge "in the guise of a challenge to the Overpayment Rule."

The Court also concluded that United failed to show that the Overpayment Rule would "inevitably" result in underpayment to MAOs. Although miscoding of diagnoses included in the traditional Medicare data might lead to such a result (as payments for treatments would be spread across a higher number of diagnoses, leading to a lower figure for payment-per-diagnosis), the evidence indicates that providers do not have adequate incentives to ensure complete coding for traditional Medicare patients and, thus, often *under-code* their diagnoses, which would lead to a higher figure for payment-per-diagnosis. Further, the Court pointed out that isolated errors in the traditional Medicare data are crunched alongside millions of other data points, may be cancelled out by isolated errors in the opposite direction, and do not themselves result in any specific, tangible overpayment. Unsupported diagnoses submitted to CMS by MAOs, on the other hand, do result in overpayment in every instance, by definition. <sup>22</sup>

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The Court also summarily rejected United's argument that the Rule violated the Medicare statute's so-called "same methodology" requirement, contained in 42 U.S.C. § 1395w-23(b)(4)(D). This provision requires CMS to use the same methodology when it annually publishes risk score data to facilitate bids from MAOs as it does when it later pays MAOs with whom it has contracted.<sup>23</sup> The Court decided that the same methodology requirement was completely unrelated to the process of calculating how much MAOs actually get paid, let alone the subsequent refund of any overpayments, and, thus, dismissed the argument out-of-hand.<sup>24</sup>

#### **Looking Forward**

While the D.C. Circuit's decision could heighten potential compliance concerns for MAOs and their business partners, CMS did not challenge and the appellate court did not review the lower court's decision to strike down the Rule's negligence standard for MAO liability under the False Claims Act. The case will head back to the District Court for entry of judgment and potentially to decide what the D.C. Circuit's decision means for the Overpayment Rule going forward. At least until that happens, however, MAOs subject to enforcement actions under the Overpayment Rule should remain steadfast that CMS's attempt to lower the scienter bar for FCA actions was unlawful and the Rule remains invalid.

In the interim, MAOs should remain vigilant in monitoring for inaccurate diagnoses, incomplete medical documentation, coding inaccuracies, and provision of requisite care identified in *bona fide* health risk assessments. Non-compliance with Medicare Advantage requirements other than the Overpayment Rule, whether identified by internal review, RADV audit, program integrity audit, or otherwise, could itself give rise to False Claims Act exposure, and remains a hot-button topic for DOJ review. For instance, MAOs should ensure they are aware of and have implemented the "Seven Fundamental Elements of an Effective Compliance Program," as described in the guidance from the Office of the Inspector General of the U.S. Department of Health and Human Services.<sup>25</sup>

With regard to the Overpayment Rule, this latest decision may mean further enforcement actions under the Overpayment Rule unless or until the District Court provides further clarity on the Rule's validity going forward. If an MAO wishes to challenge any facets of CMS's risk-adjustment model—on an actuarial equivalence basis or otherwise—it should do so when CMS annually releases its payment rates for the upcoming year, as the appellate court here suggested that such a strategy would have been more appropriate. Additionally, the harsh questioning directed at United for what appeared to the Court to be a back-door attack on more long-standing benchmarking rules and standards should serve as a warning to industry participants to monitor the development of new standards and to bring any challenges to them promptly.

Relatedly, with the continued uncertainty around compliance standards, FDRs can expect additional pressure from MAOs to implement stricter auditing processes. This pressure could begin as early as the bidding and contracting stage, so FDRs should take care to emphasize their efforts in this area as they seek out new MAO partners.

If you have any questions related to this decision or to the Overpayment Rule, please feel free to contact your usual Ropes & Gray advisor or one of the authors.

- 1. UnitedHealthcare Ins. Co. v. Becerra, No. 18-5326, 2021 WL 3573766 (D.C. Cir. Aug. 13, 2021).
- 2. 42 C.F.R. § 422.326.
- 3. *Id*.
- 4. 31 U.S.C. § 3729(b)(1).
- 5. See United States ex rel. Poehling v. UnitedHealth Grp., Inc., No. 16-cv-8697 (C.D. Cal.).
- 6. Becerra, 2021 WL 3573766, at \*12.

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- 7. 42 U.S.C. § 1395w-23(a)(1)(C)(i).
- 8. Becerra, 2021 WL 3573766, at \*15.
- 9. UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 176 (D.D.C. 2018).
- 10. Id. at 182.
- 11. Id. at 187.
- 12. Id.
- 13. Id. at 182.
- 14. *Id*.
- 15. Id. at 190-91.
- 16. See Becerra, 2021 WL 3573766, at \*9-10.
- 17. Becerra, 2021 WL 3573766, at \*14.
- 18. *Id*.
- 19. Id. at \*2.
- 20. Id. at \*18.
- 21. Id. at \*16.
- 22. Id. at \*18.
- 23. 42 U.S.C. § 1395w-23(b)(4)(D).
- 24. Becerra, 2021 WL 3573766, at \*19.
- 25. Health Care Compliance Program Tips, Office of the Inspector General of the U.S. Dep't of Health and Human Services, <a href="https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf">https://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf</a>.
- 26. See Becerra, 2021 WL 3573766, at \*2.