

D.C. District Court Vacates 60-Day Medicare Advantage Overpayment Rule

IN SHORT

The Situation: In 2016, several Medicare Advantage ("MA") organizations challenged a 2014 final rule promulgated by the Center for Medicare Services ("CMS") that broadly subjected MA organizations to potential liability under the False Claims Act for any diagnostic code submitted to CMS for payment that lacked adequate documentation in a patient's medical chart, if the organization: (i) determined or "should have determined through the exercise of reasonable diligence" that the code was not adequately documented; and (ii) did not repay CMS within the prescribed period.

The Result: The district court granted a sweeping victory to the MA organizations, holding that the rule—and the process that adopted it—was inconsistent with statutory requirements and failed to pass muster under the Administrative Procedure Act ("APA").

Looking Ahead: While the decision limits its substantive holding to vacating the overpayment rule in the MA context, its broad bases for vacating the rule likely provide a roadmap to challenge other similar rules and policies under the APA.

In 2016, several MA organizations under the UnitedHealth Group umbrella banded together and filed suit against the Department of Health and Human Services under the APA. They took aim at a final rule, adopted in 2014, that provided that any diagnostic code submitted by MA organizations to CMS for payment that was inadequately documented in a patient's medical chart could result in an "overpayment" for False Claims Act purposes if "identified" by the insurer and not repaid in the period prescribed by the rule. The rule further provided that an overpayment was "identified" whenever a MA insurer determined, or "should have determined through the exercise of reasonable diligence," that it had received an overpayment. The rule 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."

UnitedHealth alleged CMS's rule adopted a negligence standard for purposes of False Claims Act liability, a lower standard than the knowledge requirement in the Act itself. UnitedHealth also alleged that the rule would violate the statutory mandates of "actuarial equivalence" and "same methodology" because the rule would result in MA insurers having to meet a higher standard to receive and retain payments than that which CMS applies to its payments to fee-for-service providers under traditional Medicare.

Finally, UnitedHealth argued that CMS adopted the rule in an arbitrary and capricious manner, in violation of the APA. In her opinion of September 7, 2018, Judge Collyer agreed with UnitedHealth on all fronts. Her opinion vacates, retroactively to its inception, the 2014 overpayment rule and results in a clear win for MA organizations.

What can *UnitedHealthcare* teach us? While the opinion itself is limited to the 2014 overpayment rule applicable to MA organizations, the case, and certainly Judge Collyer's opinion, likely will have a broader application. First, the opinion's language that CMS unlawfully adopted "more stringent standards" for "impos[ing] [False Claims Act] consequences through regulation"—i.e., a "negligence standard"—will undoubtedly be cited in future challenges to administrative rules, which may depart from the strictures of the statutory mandate.

Next, the opinion sets forth helpful case law on certain statutory concepts, including "actuarial equivalence" and "same methodology," and provides a robust framework to challenge other rules under the APA. As Judge Collyer's decision explains, such a framework can include showing that CMS's (or other relevant agency's) new rule or policy: (i) "establishes a system" where a statutory mandate cannot be achieved; (ii) contains "no legitimate reason" for the



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change; (iii) "extends far beyond" the statute the rule is intended to implement (e.g., imposes a negligence standard in this context); or (iv) reflects "an interpretation that significantly departs from the one proposed."

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THREE KEY TAKEAWAYS

1. The 2014 overpayment rule regarding Medical Advantage organizations is vacated.
2. An administrative rule that essentially adopts a lesser standard in the False Claims Act context than the recklessness standard adopted by the courts is suspect.
3. *UnitedHealthcare* may provide a roadmap for rejecting blanket deference to an agency's rulemaking authority, laying out a robust framework to hold an agency to its responsibilities under the APA.



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