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Litigation and agency actions heighten Medicare Advantage plans' FCA risks

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In recent months, Medicare Advantage plans have seen significant shifts in the high-stakes landscape of the risk adjustment system. For one, in July, Attorney General Merrick Garland rescinded a former Department of Justice (DOJ) policy that limited the role of agency guidance in enforcement actions.[1] Now, DOJ attorneys are encouraged to liberally cite to and rely on such guidance—a particularly troubling result for Medicare Advantage plans embroiled in False Claims Act (FCA) litigation that turns on whether the plans knowingly failed to comply with a regulation or contract provision. And in August, the D.C. Circuit's decision in *UnitedHealthcare Insurance Company et al. v. Becerra*[2] unwound UnitedHealth Group's (UnitedHealth) successful challenge to the Medicare Advantage overpayment rule as the Court of Appeals determined that the rule does not violate the Medicare statute's actuarial equivalence requirement. This decision represented a major win for the DOJ and qui tam whistleblowers looking to sue providers or Medicare Advantage plans for failure to report and return overpayments based on unsupported diagnoses. Together, DOJ's course reversal on agency guidance and the D.C. Circuit's holding in *Becerra* indicate that Medicare Advantage plans may find themselves in the crosshairs of the DOJ and qui tam whistleblowers who have brought or are looking to bring FCA suits based on alleged Medicare Advantage fraud, with the added burden of defending against claims that are based on both binding law and nonbinding subregulatory guidance.

DOJ's rescission of agency guidance policy

After a wave of defense-friendly policies under the Trump administration, DOJ reversed its course on agency guidance, enabling DOJ attorneys to try once again to bolster weak FCA cases by citing to nonbinding agency guidance. In a July 1, 2021, memorandum regarding issuance and use of guidance documents by DOJ (Garland Memo),[3] Attorney General Merrick Garland rescinded DOJ's purportedly "overly restrictive" policy that prohibited using noncompliance with agency guidance as a basis for enforcement actions, explaining that the prior policy "hampered Department attorneys when litigating cases where there is relevant agency guidance." Though the Garland Memo acknowledges long-standing U.S. Supreme Court precedent that "guidance documents 'do not have the force and effect of law,'" it paradoxically encourages DOJ attorneys to liberally cite to

or rely upon agency guidance in litigation.

The Garland Memo represents DOJ's buyer's remorse following previous memoranda issued by former Attorney General Jeff Sessions and former Associate Attorney General Rachel Brand (Sessions Memo and Brand Memo, respectively). The November 16, 2017, Sessions Memo regarding prohibition of improper guidance documents barred DOJ from using its *own* guidance documents to create de facto obligations, standards, or rights, emphasizing that "guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch."[4] The January 25, 2018, Brand Memo, issued to U.S. Attorneys and "Heads of Civil Litigating Components," expanded the Session Memo's prohibition to guidance from *other* agencies in affirmative civil enforcement actions, specifying that DOJ "should not treat a party's noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation."[5] Though the Brand Memo did not render agency guidance completely moot—indeed, it specifically provided that DOJ "may use evidence that a party read such a guidance document to help prove that the party had the requisite knowledge of [a] mandate" explained or paraphrased in the guidance document—it certainly minimized its role in FCA litigation and other enforcement actions.

In February 2018, the *Justice Manual* was revised to incorporate the Brand Memo policy and expand it to criminal enforcement.[6] And in October 2019, Executive Order 13891, titled "Promoting the Rule of Law through Improved Agency Guidance Documents," further incorporated this policy, explaining that "agencies have sometimes used [their authority to issue nonbinding guidance] inappropriately in attempts to regulate the public without following the rulemaking procedures of the APA [Administrative Procedure Act]."[7]

Despite DOJ's prior extensive efforts to ensure that only binding regulations and statutes form the basis for proving violations of applicable law, President Biden rescinded Executive Order 13891 on his first day in office by way of Executive Order 13992.[8] The Garland Memo later explicitly rescinded the Sessions and Brand memos, and, on the same day the Garland Memo was issued, Attorney General Garland entered an interim final rule that implemented Executive Order 13992; revoked Executive Order 13891; rescinded any amendments to DOJ regulations pursuant to Executive Order 13891; and directed all agency heads to rescind any orders, rules, regulations, guidelines, or policies that implemented or enforced Executive Order 13891.[9] Today, the Garland Memo empowers DOJ attorneys to freely "cite [to] or rely on [guidance] documents" that "are relevant to claims or defenses in litigation" and encourages reliance "when a guidance document may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements."[10] Under this directive, DOJ attorneys will undoubtedly increase their reliance on agency guidance in enforcement actions, and guidance that is deemed "entitled to deference" may ultimately carry the weight of binding law.

UnitedHealth's loss at the D.C. Circuit

Shortly after the Garland Memo was issued, a D.C. Circuit panel unanimously reversed UnitedHealth's successful challenge to the Medicare Advantage overpayment rule (overpayment rule). The D.C. Circuit held in *Becerra* that the requirement of the Centers for Medicare & Medicaid Services (CMS) that private insurers return identified overpayments for unsupported diagnoses within 60 days did not improperly hold insurers to a higher standard than the government.

The 60-Day repayment requirement and the final overpayment rule

The overpayment rule has its roots in the Affordable Care Act, 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 results in the initial, but faulty, claim for payment becoming an FCA violation.[11] The Affordable Care Act,

however, 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 60-day shot clock. To remedy this, after a notice and comment period, CMS issued the overpayment rule in 2014.[12] Under the overpayment 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 plan determines, "or should have determined through the exercise of reasonable diligence," that it had submitted fraudulent or unsupported codes that resulted in overpayment. The preamble to the final overpayment rule 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 plan at risk of FCA liability.

District court ruling in *Azar* vacates overpayment rule

In 2018, a D.C. district court judge in *UnitedHealthcare Ins. Co. v. Azar* 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.[13] The court determined that the overpayment rule imposed an unfair standard by requiring that Medicare Advantage plans 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 traditional Medicare and Medicare Advantage plans.[14]

The district court further determined that CMS improperly exposed Medicare Advantage plans to liability under the FCA by punishing them for negligently failing to return overpayments. According to the court, the overpayment rule's negligence standard ran afoul of the FCA's requirement that a person "knowingly" submit false claims for payment to the government.

This decision marked an important win for UnitedHealth, as well as other providers and Medicare Advantage plans, 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*, 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,[15] with *U.S. ex rel. Ormsby v. Sutter Health*, denying motion to dismiss and concluding that actuarial equivalence is not a defense to an FCA claim.[16]

D.C. Circuit overturns *Azar* in *Becerra*, reinstating overpayment rule

On appeal, the D.C. Circuit overruled the lower court and determined that the overpayment rule does not violate the Medicare statute's actuarial equivalence requirement, reasoning 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."[17]

Though CMS, on appeal, did not challenge the district court's holding regarding the rule's negligence standard, UnitedHealth's argument against the rule relied on the premise that it created a sweeping obligation that effectively required Medicare Advantage plans to self-audit all their data or face FCA liability—a heavy hammer involving treble damages and penalties for each false claim. Such an obligation would leave the health plan's data set with no unverified codes, while, by stark contrast, the traditional Medicare data used to generate payment to the insurers remained unaudited and with a significant number of unsupported codes that would cause CMS to inaccurately pay insurers. The D.C. Circuit, however, disagreed with that premise, ruling that "nothing in the

Overpayment Rule obligates insurers to audit their reported data. As [the Azar Court] held ..., and CMS does not here dispute, ... the Rule only requires insurers to refund amounts they know were overpayments, i.e., payments they are aware lack support in a beneficiary's medical records. That limited scope does not impose a self-auditing mandate."[18]

The Court also ruled that nothing in the statute or the rule rendered actuarial equivalence a defense against the obligation to refund any individual known overpayment. While relying on multiple grounds to reach that conclusion, in short, the court ultimately found that the actuarial-equivalence requirement applied only to the setting of rates, not to the obligation to return payments that a plan knows to be wrong: "The 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."[19] Further, the court took issue with the practical consequences of imposing actuarial equivalence to a health plan's refund obligation, noting the "absurd consequences"[20] of an insurer being entitled to retain a payment it knew was not supported by the medical records. 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"[21] 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 payment-related data and requires Medicare Advantage plans to return to CMS any overpayments identified through the audit. Importantly, however, CMS requires that prior to assessing any overpayments due from the Medicare Advantage plan, the plan's RADV audit data must be made actuarially equivalent to traditional Medicare data. In other words, before determining whether an overpayment has been made in the context of a RADV audit, the Medicare Advantage plan's data must be adjusted to account for error levels in the traditional Medicare data set. This is precisely what UnitedHealth was seeking in application of the overpayment rule. The D.C. Circuit distinguished RADV audit procedures from the requirements of the overpayment rule, holding that RADV audits "are an error-correction mechanism that is materially distinct from the Overpayment Rule challenged here, which requires only that an insurer report and return to CMS known errors in its beneficiaries' diagnoses that it submitted as grounds for upward adjustment of its monthly capitation payments."[22]

Becerra's impact on Medicare Advantage plans

Despite CMS declining to appeal the district court's conclusion that the final rule's negligence standard was inconsistent with the FCA's scienter requirement, and the D.C. Circuit's repeated use of the phrase "known" to describe overpayments subject to the rule, the *Becerra* decision and its termination of the actuarially equivalent defense is a certain victory for DOJ and qui tam whistleblowers who have brought or will bring cases grounded on a Medicare Advantage plan'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 by adopting an unreasonable audit model. Indeed, the day the *Becerra* ruling was issued, the government and FCA defendants embroiled in major litigation on this same theory filed a joint stipulation indicating that they are presently working toward a settlement.[23] Accordingly, the *Becerra* holding makes it 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 Medicare Advantage plans audit their reported data, any plan audits or reviews undertaken should be structured so that they cannot be accused of being reckless in failing to identify such overpayments.

Compounding the impact of *Becerra* removing a significant defense from plans facing FCA actions, DOJ identified

Medicare Advantage as an area for increased targeting and enforcement before the D.C. Circuit reversed *Azar*. In December 2020, 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."[24] Further, in July 2021,[25] DOJ intervened in six complaints alleging members of the Kaiser Permanente consortium violated the FCA by submitting inaccurate diagnosis codes at an estimated 75% error rate. DOJ's October 2021 complaint-in-intervention alleged that Kaiser's "widespread and unlawful" practice of adding unsupported diagnoses to patient records caused Kaiser to receive "additional Medicare payments in the range of $1 billion."[26]

DOJ's recent about-face with respect to its treatment of agency guidance will likely also sharpen DOJ's focus on Medicare Advantage fraud and likely spur even more government and qui tam whistleblower actions. Though DOJ was not so bold in its recent complaint-in-intervention in the Kaiser Permanente cases, Medicare Advantage plans facing FCA claims can expect DOJ to return to the pre-Brand Memo citations to nonbinding agency guidance as grounds for enforcement efforts—for example, relying on the Medicare Manuals or memoranda from CMS to interpret broad language in the Social Security Act—to bolster their arguments of false certifications. DOJ's revised treatment of guidance documents will surely now trigger enforcement actions where the prior administration would have likely declined intervention. And even though the Garland Memo acknowledges that agency guidance cannot form "'the basis for an enforcement action' because such documents cannot 'impose any 'legally binding requirements' on private parties,'"[27] Medicare Advantage plans may find little solace in this concession, as many enforcement actions will settle long before the point of litigating the issue. FCA investigations alone can prove costly, and settlement is often far more attractive than litigation risking the possibility of treble damages, penalties, relators' fees and costs, the plan's litigation expenses, and reputational damage.

Conclusion

While Medicare Advantage plans now find themselves in an atmosphere of heightened risk, there are steps that plans can take that may reduce the risk of an FCA action, and nuanced defenses that may now be available as a result of the *Becerra* decision. At a minimum, though, plans would be well advised to take a careful look at their compliance policies and practices to ensure they are appropriately tailored to their current risk profiles. It is essential that plans can articulate *why* they elected to take certain actions—particularly with respect to audits – and that such actions were even-handed in their application. And, as always, plans should continue to have appropriate mechanisms in place for employees and third parties to report perceived issues and processes in place to ensure the plan addresses such information in a timely manner. In short, as it has long been, a robust, even-handed compliance approach—that accounts for the recent shift in DOJ policy and the *Becerra* holding—is the best defense against enforcement actions in the risk adjustment arena.

Takeaways

- The government and False Claims Act (FCA) relators are targeting Medicare Advantage (MA) plans risk adjustment processes, particularly retroactive chart review practices.
- Recently announced Department of Justice policies rescind pro-defendant Trump administration policies and could provide ammunition for FCA plaintiffs.
- The D.C. Circuit's recent ruling in *Azar*, at a minimum, calls into question the "actuarial equivalence" defense MA plans had until recently been using to fight off FCA actions.
- While affirming Department of Health & Human Services' 60-day overpayment rule, the *Azar* court left

unanswered the key question of when exactly an MA plan identifies an unsupported code, potentially opening a door to new defenses.

- MA plans should revisit their risk adjustment processes and related compliance policies and practices to ensure they are calibrated to current risk profiles.

1 U.S. Department of Justice, Office of the Attorney General, "Issuance and Use of Guidance Documents by the Department of Justice," memorandum, July 1, 2021, https://www.justice.gov/opa/page/file/1408606/download.
2 UnitedHealthcare Ins. Co. v. Becerra, No. 18-5326 (D.C. Cir. 2021).
3 U.S. Department of Justice, Office of the Attorney General, "Issuance and Use of Guidance Documents by the Department of Justice."
4 U.S. Department of Justice, Office of the Attorney General, "Prohibition on Improper Guidance Documents," memorandum, November 16, 2017, https://www.justice.gov/opa/press-release/file/1012271/download.
5 U.S. Department of Justice, Office of the Associate Attorney General, "Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases," memorandum, January 25, 2018, https://www.justice.gov/file/1028756/download.
6 U.S. Dep't of Just., Just. Manual §§1-19.000, 1-20.000 (2018).
7 Promoting the Rule of Law Through Improved Agency Guidance Documents, 84 Fed. Reg. 55,235 (October 15, 2019) .
8 Revocation of Certain Executive Orders Concerning Federal Regulation, 86 Fed. Reg. 7,049 (January 25, 2021) .
9 Processes and Procedures for Issuance and Use of Guidance Documents, 86 Fed. Reg. 37,674 (July 16, 2021) .
10 U.S. Department of Justice, Office of the Attorney General, "Issuance and Use of Guidance Documents," 2–3.
1142 U.S.C. § 1320a-7k(d) .
12 Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014) (codified at 42 C.F.R. § 423.360) .
13 UnitedHealthcare Ins. Co. v. Azar, No. 1:16-cv-00157 (D.D.C. 2018).
1442 U.S.C. § 1395w-23(a)(1)(C)(i) .
15 U.S. ex rel. Poehling v. UnitedHealth, 2:16-cv-08697 (C.D. Cal. 2019).
16 U.S. ex rel. Ormsby v. Sutter Health, 3:15-cv-01062 (N.D. Cal. 2020).
17 UnitedHealthcare Ins. Co. v. Becerra, D.C. Cir., at 34.
18 UnitedHealthcare Ins. Co. v. Becerra, D.C. Cir., at 31.
19 UnitedHealthcare Ins. Co. v. Becerra, D.C. Cir., at 34.
20 UnitedHealthcare Ins. Co. v. Becerra, D.C. Cir., at 36.
21 UnitedHealthcare Ins. Co. v. Becerra, D.C. Cir., at 6.
22 UnitedHealthcare Ins. Co. v. Becerra, D.C. Cir., at 48.
23 U.S. ex rel. Ormsby v. Sutter Health.
24 U.S. Department of Justice, "Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute," December 2, 2020, https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act.
25 U.S. Department of Justice, "Government Intervenes in False Claims Act Lawsuits Against Kaiser Permanente Affiliates for Submitting Inaccurate Diagnosis Codes to the Medicare Advantage Program," news release, July 30, 2021, https://www.justice.gov/opa/pr/government-intervenes-false-claims-act-lawsuits-against-kaiser-permanente-affiliates.
26 United States' Compl.-in-Intervention, United States ex rel. Osinek v. Kaiser Permanente, 3:13-cv-03891-EMC (N.D. Cal. 2021), https://www.justice.gov/opa/press-release/file/1444936/download.

27 U.S. Department of Justice, Office of the Attorney General, "Issuance and Use of Guidance Documents," 2.