Patterson Belknap

Litigation Alert
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The Fourth Circuit Broadly Interprets "Inducement" and "Remuneration" Under the Anti-Kickback Statute and Creates a Circuit Split

On January 23, 2025, in *Pharmaceutical Coalition for Patient Access v. United States*, the Fourth Circuit held that a proposed patient assistance program, which would help cancer patients afford certain oncology drugs, would violate the Anti-Kickback Statute ("AKS").[1] In so holding, the panel underscored the broad reach of the AKS in concluding that even charitable subsidies aimed at defraying low-income patients' out-of-pocket costs can constitute illegal "remuneration" that improperly "induces" federally reimbursable drug purchases. The Fourth Circuit's expansive interpretation of the AKS creates a circuit split in what constitutes illegal "remuneration" and offers a stark reminder that patient assistance programs must be carefully structured to minimize AKS exposure.

Takeaways

- *Pharmaceutical Coalition* creates a circuit split with the Sixth Circuit on the interpretation of "any remuneration" in the AKS. The Fourth Circuit broadly interpreted this term to encompass any "payment or compensation" and held, contrary to a recent Sixth Circuit decision,[2] that a value transfer does not need to corrupt the medical decision-making process to qualify as AKS remuneration.[3] The court concluded that "any" expands the scope of "remuneration" to include any form of remuneration beyond the statute's three examples (i.e., kickback, bribe, or rebate).

- According to the Fourth Circuit, to qualify as inducement under the AKS, remuneration need not "induce" a separate criminal act. It is enough that the remuneration would influence the purchase of federally reimbursable healthcare goods and services.

- The Fourth Circuit held that a patient assistance program funded by drug manufacturers would constitute quid pro quo in the AKS context so long as the program subsidizes the cost of drugs from the funding manufacturers, even if the program is agnostic to which specific drug a patient selects.

Background

Pharmaceutical Coalition for Patient Access (the "Coalition"), a charitable organization whose members include drug manufacturers, proposed a patient assistance program to help Medicare beneficiaries afford certain oncology drugs using funds provided by the manufacturers. The program would provide co-pay subsidies to Medicare Part D beneficiaries who met the following criteria: (1) a cancer diagnosis; (2) a household income between 150 percent and 350 percent of the federal poverty line; (3) a prescription for a Part D oncology drug produced by a participating manufacturer; and (4) approval of coverage of the drug from a patient's Part D plan.

In January 2022, the Coalition sought an Advisory Opinion[4] from the Office of the Inspector General for the Department of Health and Human Services ("OIG") to ensure that the program would not violate the AKS's prohibition against "knowingly and willfully offer[ing] or pay[ing] any remuneration (including

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[1] *Pharm. Coal. for Patient Access v. United States*, 126 F.4th 947 (4th Cir. 2025).
[2] *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1048, 1051 (6th Cir. 2023).
[3] *Pharm. Coal. for Patient Access*, 126 F.4th at 958–61.
[4] Given the statute's criminal penalties, Congress permits parties to seek advisory opinions from OIG on whether a proposed program would violate the statute. 42 U.S.C. § 1320a-7d(b). Advisory opinions bind OIG and the requesting party. *Id*.

any kickback, bribe, or rebate)" to "induce" a person to, e.g., buy a federally reimbursable healthcare product.[5]

In September 2022, OIG issued an advisory opinion, finding that the Coalition's program could violate the AKS because the Coalition would pay subsidies (i.e., remuneration) to offset Medicare beneficiaries' out-of-pocket costs for co-pay payments. This would induce those patients to purchase the participating manufacturers' oncology drugs, which in turn would lead to a greater number of claims to Part D to cover the balance of the drugs' costs not covered by co-pays.[6]

In November 2022, the Coalition sued in federal court to challenge OIG's application of the AKS, arguing that the statute requires a showing of a quid pro quo exchange and corruption, and that the government failed to show that the proposed program involved either.[7] In January 2024, the district court rejected the Coalition's reading of the AKS and its challenge to OIG's unfavorable advisory opinion, granting OIG's motions to dismiss for lack of subject matter jurisdiction and for summary judgment.[8] The Coalition appealed.

The Fourth Circuit's Decision

On appeal, the Coalition asserted three arguments based on the statutory text for why its proposed program would not run afoul of the AKS:[9]

(1) "Induce" in the AKS is a term of art that means, in the criminal law context, "intentional encouragement of an unlawful act" and "the provision of assistance to a wrongdoer with the intent to further an offense's commission." But the Coalition's charitable program would not encourage any unlawful act.

(2) "Remuneration" is prohibited under the AKS only if it corrupts medical decision-making.

(3) The Coalition's proposed program would not involve any prohibited quid pro quo because its subsidies for prescriptions would not be contingent on the purchase of specific individual drugs.

The Fourth Circuit rejected the Coalition's arguments. First, the court held that "induce" should be construed in view of its ordinary meaning and not its "specialized criminal law meaning," i.e., as conduct that "leads or tempts to the commission of a crime."[10] For example, "a party can violate the [AKS] by offering remuneration without a corresponding violation by the offeree" if the offeree did not seek or accept the remuneration.[11] To wit, if a manufacturer offered remuneration to a physician to furnish a federally reimbursable healthcare service with the requisite intent, and the physician refused the remuneration but furnished the service anyway based on her independent professional judgment, the offerer, but not the physician, would have violated the AKS. This hypothetical, according to the court, illustrates that the AKS "prohibits inducement accompanied by a specific motive, which does not necessarily lead to an independent crime."[12]

Second, after reviewing the statutory text, dictionaries, canons of construction, and case law, the court held that "remuneration" has an "ordinary meaning of payment or compensation" and is not limited to payment that "corrupts the medical decision-making process."[13] Citing a recent Second Circuit

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[5] *Id.* § 1320a-7b(b)(2).
[6] *Pharm. Coal. For Patient Access v. Dep't of Health & Hum. Servs.*, No. 3:22-cv-714, 2024 WL 187707, at *4 (E.D. Va. Jan. 17, 2024).
[7] *Id.* at *5.
[8] *Id.* at *22.
[9] *Pharm. Coal. for Patient Access*, 126 F.4th at 953.
[10] *Id.* at 953–56.
[11] *Id.* at 955.
[12] *Id.* at 956.
[13] *Id.* at 958.

decision[14] that also refused to impute an element of corruption to "remuneration," the Court held that any limitation to "corrupt" transactions is "glaringly absent" from the AKS.[15] In addition, the Court noted that Congress's addition of terms of enlargement to the AKS, which now prohibits "*any* remuneration (*including* any kickback, bribe, or rebate)," indicates that "remuneration" should be broadly construed, and not limited to the three examples in the parenthetical.[16]

In interpreting "remuneration" broadly, the Fourth Circuit expressly disagreed with the Sixth Circuit's 2022 decision *U.S. ex rel. Martin v. Hathaway*.[17] In *Martin*, the Sixth Circuit held that "remuneration" means "just payments and other transfers of value," not "any act that may be valuable to another." The Sixth Circuit found that the term "any" preceding "remuneration" in the AKS does not broaden the scope of "remuneration" but instead "proves only that the statute covers remuneration of any type (cash, services, goods)."[18] Further, while the statute does not mention corruption, the Sixth Circuit emphasized the link between the AKS and corruption, noting that the statute's purpose is to discourage healthcare decisions made based on financial motives rather than medical necessity, that a broad reading of the AKS would sweep in "[m]uch of the workaday practice of medicine," and that its narrow interpretation of "remuneration" "leaves plenty of room to target genuine corruption."[19] But the Fourth Circuit was unpersuaded, concluding that *Martin*'s reasoning would render certain statutory text redundant and ignore Congress's terms of enlargement.

Lastly, the Fourth Circuit declined to rule whether the AKS includes a quid pro quo requirement, joining several other courts that have avoided answering this question.[20] Instead, the Fourth Circuit assumed for the purposes of its analysis that the AKS imposes such a requirement and, so assuming, held that the program would constitute an impermissible quid pro quo. The court noted that the program would use funding from drug manufacturers to subsidize co-pay payments for prescriptions of those manufacturers' drugs, and the subsidies would not be contingent on the purchase of specific, individual drugs. Applying the logic of anti-bribery law, the Court concluded that while the program's subsidies are agnostic to which specific drug participating patients would eventually purchase, they still qualify as payments to induce the use of one or more of those drugs. In other words, the program improperly "offer[s] subsidies (quid) for a beneficiary's purchase of a covered drug, or at least one of a group of covered drugs (quo)."[21]

Conclusion

The Fourth Circuit took an expansive approach to construing the AKS, creating a split with the Sixth Circuit's narrow interpretation of "remuneration"—and, in turn, creating different standards for AKS exposure in different parts of the country. The Court's interpretations of "inducement" and "remuneration" potentially sweep in a broad range of transactions and arrangements involving value transfers in connection with the provision of federally reimbursable medical goods and services. The decision also leaves unaddressed whether AKS liability requires proof of quid pro quo. Such a requirement would raise the bar for the government and whistleblowers by adding an extra hurdle to prove liability under the statute. Federal courts are split on this issue[22] and the Supreme Court has not

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[14] *Pfizer, Inc. v. U.S. Dep't of Health & Human Servs.*, 42 F.4th 67, 78 (2d Cir. 2022).
[15] *Pharm. Coal. for Patient Access*, 126 F.4th at 959.
[16] *Id.* at 960 (citing 2 U.S.C. § 1320a-7b(b)(2) (emphasis added).
[17] *Martin*, 63 F.4th at 1051.
[18] *Id*.
[19] *Id.* at 1052–55.
[20] *See Pfizer, Inc.*, 42 F.4th at 74 (2d Cir. 2022) ("For the purposes of this appeal, we do not need to decide whether the AKS contains a quid pro quo element."); *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 93 (3d Cir. 2018) ("[W]e express no view on whether [defendant's] charitable contributions were illegal kickbacks under the Anti–Kickback Statute.").
[21] *Pharm. Coal. for Patient Access*, 126 F.4th at 963.
[22] *Compare United States v. Medco Health Sys., Inc.*, 223 F. Supp. 3d 222, 227 (D.N.J. 2016) ("[A] plaintiff must establish that defendants violated the AKS through its alleged quid pro quo arrangement . . . ."), *aff'd sub nom. United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018) *with Pfizer Inc. v. United States Dep't of Health & Hum. Servs.*, No. 1:20-cv-4920, 2021 WL

provided guidance. It remains to be seen whether the Supreme Court will weigh in to clarify any of these unsettled issues.

In addition, this decision has significant implications for programs designed to help patients afford their medicines, including co-pay assistance programs. First, it reflects OIG's continued concerns regarding perceived abuses by patient assistance programs, especially those that permit Medicare or Medicaid beneficiaries to participate. Particular scrutiny of co-pay assistance programs may increase going forward in light of the Inflation Reduction Act's new $2,000 cap on out-of-pocket expenses for Medicare Part D prescription drugs, which shifts a greater portion of the cost burden onto Medicare with each prescription.[23] Second, the decision underscores that even charitable intentions, and the absence of any evidence indicating healthcare decision-making was skewed, are not necessarily defenses to potential AKS liability. Healthcare companies and hospitals should take care to review their patient assistance programs to ensure that they do not directly or indirectly encourage the increased utilization of drugs or services that are reimbursable by federal healthcare programs.

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4523676, at *13 (S.D.N.Y. Sept. 30, 2021) (holding that quid pro quo is not a requirement because "the word 'inducement' implies a 'one-way' transaction), *aff'd sub nom. Pfizer, Inc*, 42 F.4th at 69.

[23] Inflation Reduction Act and Medicare, United States Department of Health and Human Services, https://www.hhs.gov/inflation-reduction-act/index.html (last visited Feb. 10, 2025).