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BLOG

E.D. Virginia Endorses Broad Interpretation of Anti-Kickback Statute

APRIL 17, 2024

I. OVERVIEW

The U.S. District Court for the Eastern District of Virginia is the latest court to weigh in on the continuing debate surrounding the scope of the Federal Anti-Kickback Statute (AKS) as it applies to patient assistance programs (PAPs). In a lengthy opinion issued in January 2024, the court endorsed the broad interpretation advanced by the government, expressing little sympathy for the legal or policy arguments advanced by the plaintiffs, a coalition of pharmaceutical manufacturers. The coalition has indicated it will appeal the case to the Fourth Circuit.

The opinion is significant for all entities doing business in the health care sector, as it underscores the broad reach of the AKS. For entities operating (or considering) PAPs, the opinion confirms the need to proceed with care and in alignment with applicable guidance. Notably, while the opinion does not address relevant changes to Part D cost sharing adopted as part of the Inflation Reduction Act of 2022 (IRA), a new Advisory Opinion issued by the Department of Health and Human Services Office of the Inspector General (HHS-OIG) on April 8, 2024, suggests that the IRA's changes may impact the government's perspective on the AKS risks presented by PAPs in the future.

II. PHARMACEUTICAL COALITION FOR PATIENT ACCESS V. UNITED STATES

In January 2022, Plaintiff Pharmaceutical Coalition for Patient Access (PCPA) submitted a request to HHS-OIG, seeking an advisory opinion regarding its proposed coalition model PAP that was designed to help Medicare Part D enrollees diagnosed with cancer more easily afford their oncology medications. Under Part D, these medications can cost enrollees tens of thousands of dollars out of pocket annually.

Under the proposed PAP, PCPA would provide copay subsidies to Medicare Part D enrollees who met the following criteria: (1) a cancer diagnosis; (2) a household income between 150% and 350% of the federal poverty line; (3) a prescription for a Part D oncology drug produced by a participating manufacturer; and (4) initial approval of the coverage of the drug from their Part D plan. Qualified enrollees would pay just $35 per month for branded drugs ($10 for generic drugs), plus either 25% or 10% of their applicable co-insurance obligation, depending on the enrollee's financial need. Any drug manufacturer with oncology products reimbursed by Medicare Part D could participate in the PCPA arrangement. Importantly, participating manufacturers would only subsidize costs associated

with their own products. Thus, PCPA would effectively serve as a "middleman" between drug manufacturers and Medicare Part D enrollees.

In September 2022, HHS-OIG issued an unfavorable Advisory Opinion (No. 22-19), (2022 Advisory Opinion) finding that PCPA's proposed PAP "would fit squarely within" the AKS's prohibitions if the requisite intent were present. Specifically, HHS-OIG found that participating manufacturers' payments to PCPA would be "calculated to induce Part D enrollees to purchase their Part D oncology drugs," and that the proposed payment program was "highly suspect . . . as a way to sidestep the cost-sharing structure that Congress included in the standard Part D benefit" and would consequently "present significant risk of increased drug prices." *Pharm. Coal. For Patient Access v. Dep't of Health & Hum. Servs.*, 2024 WL 187707, at *4 (E.D. Va. Jan. 17, 2024).

In November 2022, PCPA filed suit, alleging that HHS-OIG's unfavorable 2022 Advisory Opinion was arbitrary and capricious or contrary to law. PCPA advanced four main arguments:

> (1) the opinion is contrary to law because HHS-OIG's interpretation runs contrary to the plain language of the AKS;
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> (2) the opinion is arbitrary and capricious because it treats PCPA's proposal in an unjustifiably dissimilar fashion to similarly situated parties;
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> (3) a 2005 Special Advisory Bulletin renders the negative opinion arbitrary and capricious;
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> (4) the negative opinion infringes upon PCPA's First Amendment free speech rights.

On January 17, 2024, the Eastern District of Virginia issued its 47-page decision on the parties' cross-motions for summary judgment in *Pharmaceutical Coalition for Patient Access v. Department of Health and Human Services*. The Court granted summary judgment in favor of the United States, rejecting all four of PCPA's arguments and finding that the 2022 Advisory Opinion was not arbitrary, capricious, or contrary to law. On March 15, 2024, PCPA filed a Notice of Appeal.

A. Plain Language of the AKS

The Court rejected PCPA's argument that the 2022 Advisory Opinion is contrary to the plain text of the AKS. The Court found it was unnecessary to decide whether the statute's "any remuneration . . . to induce" language necessarily connotes a quid pro quo requirement because, according to PCPA's own description, the proposed PAP *would* constitute a quid pro quo. Specifically, participating manufacturers would pay remuneration, in the form of cost-sharing subsidies, to Medicare Part D enrollees so that enrollees would purchase manufacturers' federally reimbursable products. The Court was unpersuaded by PCPA's position that the proposed PAP could not constitute a quid pro quo, because enrollees would have a number of drugs to choose from, noting that "[e]ach participating manufacturer would furnish subsidies (quid) for (pro) the purchase of its drugs (quo)." *Id.* at *5.

The Court rejected PCPA's argument that the term "induce" requires a corrupt intent with respect to the remuneration, finding that the ordinary meaning of the word "induce" is to "entic[e] or persuad[e] another person to take a certain course of action," which is neutral with respect to intent. *Id.* at *7. Likewise, the Court rejected PCPA's argument that the parenthetical phrase "any remuneration (including any kickback, bribe, or rebate)" limits the AKS's scope to only "corrupt" remuneration. The Court reasoned that the phrase "any remuneration" is extremely broad and has no corrupt connotation, and that the statute's parenthetical starts with the word "including," which is a term of enlargement, not limitation. *Id.* at *10.

The Court also rejected PCPA's argument that its narrow interpretation is necessary to prevent absurd results. PCPA claimed that the 2022 Advisory Opinion's interpretation of the AKS could criminalize the act of "a generous son who helps cover the cost of his elderly mother's medical treatment." *Id.* at *12. However, the Court reasoned that this type of situation is unlikely to result in an AKS violation because a concerned son would presumably pay for the treatment regardless of whether the drug was federally reimbursable and would not have the same financial interest that a pharmaceutical manufacturer has in federal-government reimbursement for drugs. On this basis, the

generous son would not have the requisite intent under the AKS, which requires that a party act knowingly and willfully.

B. Dissimilar Treatment to Similarly Situated Parties

The Court dismissed, without reaching the merits, PCPA's arguments that the 2022 Advisory Opinion is arbitrary and capricious because it treats PCPA dissimilarly to other, similarly situated parties. The Court found it did not have subject matter jurisdiction to review PCPA's first dissimilar-treatment claim because the decision to which PCPA claimed the 2022 Advisory Opinion is dissimilar is a decision regarding the imposition of administrative sanctions, and such decisions are committed to agency discretion by law. The Court also declined to consider PCPA's second dissimilar-treatment claim, relating to safe harbors for Part D copayments, because PCPA did not raise this argument during administrative proceedings. The Court found that the HHS-OIG advisory opinion process is adversarial and thus issue exhaustion was required, because PCPA, as the requestor of the Advisory Opinion, bore responsibility to develop issues for the adjudicator's consideration.

C. Failure to Follow 2005 Special Advisory Bulletin

The Court rejected PCPA's argument that HHS-OIG's 2022 Advisory Opinion did not follow its Special Advisory Bulletin guidance issued in 2005, finding that the 2005 Bulletin did not take a definitive stance on the legality of any particular PAP proposal. Instead, the Court found that the Bulletin made clear that the ultimate legality of a particular PAP under the AKS would require a case-by-case analysis of all relevant facts and circumstances. Thus, the Court held that HHS-OIG did not make a policy or position change without adequate explanation.

D. Infringement on First Amendment Rights

Finally, the Court rejected PCPA's argument that the 2022 Advisory Opinion impermissibly infringes on PCPA's First Amendment rights. While the Court acknowledged that solicitation of charitable contributions is protected speech, it held that this does not provide blanket protection to all conduct related to solicitation of money. The Court noted that the 2022 Advisory Opinion would not hamper PCPA's ability to communicate about oncology treatments, or any number of related topics—it only prevented the provision of remunerations to induce certain purchases.

III. PFIZER V. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Eastern District of Virginia's reasoning in *PCPA* largely mirrors that of the Second Circuit in *Pfizer v. United States Department of Health and Human Services*, 42 F.4th 67 (2d Cir. 2022). In that decision, Pfizer challenged a 2020 HHS-OIG Advisory Opinion concluding that Pfizer's proposed PAP—which would offer subsidy cards to financially needy Medicare Part D enrollees prescribed its drug, Tafamidis—would violate the AKS if the requisite intent were present. The Second Circuit affirmed the lower court's grant of summary judgment to the United States, rejecting many of the same arguments advanced by PCPA.

IV. KEY TAKEAWAYS

These recent decisions reflect the government's continued concerns regarding perceived abuses by PAPs. In particular, the government has expressed significant concern that these programs can lead to increased drug prices by undermining the cost sharing that Congress built into the Part D benefit. As of now, it is not clear whether the new caps on Part D beneficiary copayments that were adopted as part of the IRA will shift the government's views on this point, but a new Advisory Opinion issued by HHS-OIG on April 8, 2024, suggests change may be coming.

Under the IRA, beneficiary Part D cost sharing is capped at $2,000 per year beginning in 2025. This cap will dramatically lower out-of-pocket expenses under Part D for many beneficiaries. Nonetheless, from the beneficiary's perspective, the new cap may not meaningfully move the needle on affordability, as $2,000 out of pocket annually is likely still cost prohibitive for many beneficiaries.[4] Importantly, the new cap also arguably stunts the ostensible price-limiting impact of Part D cost sharing, which has been a key factor that HHS-OIG has cited when articulating its concerns regarding PAPs.

In its most recent Advisory Opinion, HHS-OIG issued a favorable opinion regarding a PAP's operation of certain funds for patients with rare diseases. However, the agency took the highly unusual step of setting an expiration date

for the Opinion, sunsetting it on January 1, 2027—two years after the IRA out-of-pocket cap goes into effect. HHS-OIG stated that the IRA's changes to Part D could ease demand for cost-sharing subsidies provided by PAPs and that such a change in could impact (i) the amounts and types of donations the PAP receives, (ii) the proportion of funding that each disease fund spends on various categories of expenses, and (iii) the number of patients that meet the financial-need criteria. HHS-OIG concluded that these changes could "alter [its] assessment of the balance of benefits and risks" presented by the PAP. As such, the Opinion will expire two years after the implementation of the IRA out-of-pocket cap. The agency indicated that it selected this time frame to allow the PAP that requested the Opinion "sufficient time and data to submit a new advisory opinion request or request for modification of this opinion (as desired)." Based on these statements, it is unclear whether HHS-OIG intends to issue updated guidance regarding PAPs and whether other existing favorable advisory opinions for PAPs that are premised on the current, pre-IRA Part D benefit design may be impacted by HHS-OIG's evolving views. Stakeholders should pay close attention to ongoing developments in this area.

More generally, the PCPA opinion underscores the broad reach of the AKS. All health care industry stakeholders should be diligent in thoughtfully structuring arrangements involving remuneration between parties in a position to refer, order, or recommend covered items and services.

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[1] In its briefing, PCPA acknowledged that the IRA "promises some relief to Part D beneficiaries, but its assistance is implemented only on a delayed basis, and, even when fully implemented, the assistance that it provides will still leave many Part D beneficiaries unable to secure access to the cancer and other drugs they desperately need." PCPA notes that according to a leading study, as many as 41% of all the tested patients with cancer abandoned their medication if their out-of-pocket costs were between just $500.01 and $2,000. *See* Complaint, *PCPA v. HHS*, 3:22-cv-714 (citing Jalpa A. Doshi, et al., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. of Clinical Oncology 5 (Feb. 10, 2018), https://ascopubs.org/doi/pdf/10.1200/JCO.2017.74.5091?role=tab).

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