

Legal Challenge to Patient Assistance Programs Puts Anti-Kickback Statute in the Spotlight

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To help cover consumers' out-of-pocket costs for expensive prescription drugs or other medical items or services, [patient assistance programs](#) (PAPs) may offer free drugs or financial assistance to eligible individuals, including individuals covered by federal health care programs like [Medicare](#). PAPs may also provide financial subsidies for high-cost medications used to treat cancer, diabetes, or other serious or chronic conditions. The Office of the Inspector General of the Department of Health and Human Services ([OIG](#)) and [others](#) have expressed the view that, while PAPs may provide valuable safety net assistance for patients, these kinds of programs may pose a risk of violating certain health care fraud and abuse laws, including the federal [Anti-Kickback Statute](#). Some PAPs and their contributors have sought judicial review of the application of the Anti-Kickback Statute and other anti-fraud and abuse provisions to these assistance arrangements. In January 2025, in [Pharmaceutical Coalition for Patient Access v. United States](#), the U.S. Court of Appeals for the Fourth Circuit concluded that [OIG](#) properly determined that the PAP's arrangement could violate the Anti-Kickback Statute. This Legal Sidebar provides background on PAPs and the Anti-Kickback Statute, discusses *Pharmaceutical Coalition*, and provides selected legal considerations for Congress.

Background

Patient Assistance Programs (PAPs)

As described in this CRS report, medical product manufacturers provide billions of dollars in financial assistance each year to eligible individuals to help pay for prescription drugs or other health care expenses. One way that assistance is offered is through PAPs, some of which [are operated](#) through foundations or charities that receive funding from medical product makers. These programs [may offer](#), or [propose to offer](#), free products, insurance co-payment assistance, or other types of financial support to individuals, typically based on eligibility criteria such as income, medical need, or insurance status. One industry report [concluded](#) that in 2022, manufacturers spent \$18.7 billion on drug co-payment assistance. While PAPs may help individuals access expensive, and sometimes unaffordable, medical treatments,

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federal government agencies and legal commentators raise concerns that some arrangements may potentially violate health care fraud and abuse laws, including the Anti-Kickback Statute. Proponents of these views argue that some PAPs may improperly steer federal health care program beneficiaries to use a particular manufacturer's products and possibly trigger higher costs for the programs. This might occur if, for example, a PAP subsidizes the cost of a more expensive medication when lower-cost alternatives are available).

The Federal Anti-Kickback Statute

Congress enacted the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) to restrict improper influences on health care provider decisionmaking and prevent overutilization in federal health care programs such as Medicare and Medicaid. In relevant part, this statute generally establishes criminal penalties for persons who knowingly and willfully offer or pay “remuneration” to “induce” a person to refer a patient for covered health care services or otherwise generate business reimbursable under a federal health care program. Specifically, the Anti-Kickback Statute provides:

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made . . . under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made . . . under a Federal health care program,

shall be guilty of a felony

Persons found guilty of violating the statute may be subject to criminal fines and imprisonment, exclusion from participation in federal health care programs, and potential civil liability under the Federal False Claims Act. The Department of Justice enforces the Anti-Kickback Statute and has recovered billions of dollars in settlements related to PAPs (*see, e.g., here and here*).

Additionally, because of the steep penalties at stake with the Anti-Kickback Statute, Congress created a mechanism through which parties can request advisory opinions from OIG that resolve whether certain activities violate the anti-kickback statute and other health care fraud and abuse provisions. These opinions are binding on both OIG and the party requesting the opinion. Several entities that operate PAPs have sought advisory opinions to protect their arrangements from enforcement action. In some opinions related to PAPs, OIG has determined that, while the program in question would generate prohibited remuneration under the Anti-Kickback Statute, the agency would not impose sanctions on the requesting party (generally because, in OIG's view, the arrangement met certain “safeguards,” articulated in agency guidance, such as the awarding of assistance without consideration of the treatment regimen prescribed for a particular patient). In other instances, OIG has issued an unfavorable opinion for these entities, and some of these entities have then challenged these opinions in court.

Recent Litigation over PAPs: *Pharmaceutical Coalition for Patient Access v. United States*

In *Pharmaceutical Coalition*, a charitable organization financed exclusively by oncology drug manufacturers requested an advisory opinion from OIG concerning a proposed patient subsidy arrangement. Under the arrangement, the organization would help eligible Medicare beneficiaries pay for oncology medications by providing drug cost-sharing subsidies if the beneficiary had, among other things, a household income between 150% and 350% of the federal poverty level and a prescription for an oncology drug produced by a PAP-participating manufacturer. OIG concluded in its opinion that the

organization's arrangement could violate the Anti-Kickback Statute, due in part to the fact that the funding manufacturers would only provide financial assistance through the organization for their own oncology products (i.e., a manufacturer would not subsidize other manufacturers' products). This arrangement, OIG [explained](#), included many of the "hallmark risks of fraud and abuse that the Federal anti-kickback statute was designed to prevent," including possible increased costs to Medicare, the potential for patient steering, and anti-competitive effects. The organization sued, claiming that the unfavorable advisory opinion was an abuse of agency discretion under the [Administrative Procedure Act](#). The U.S. District Court for the Eastern District of Virginia [rejected](#) the PAP's claims and dismissed the case, and the U.S. Court of Appeals for the Fourth Circuit (Fourth Circuit) affirmed the decision.

The appeals court's [analysis](#) in *Pharmaceutical Coalition* largely turned on the meaning of the words "induce" and "remuneration," as used in the Anti-Kickback Statute. As noted, the statute generally establishes criminal penalties for persons who knowingly and willfully offer or pay remuneration to induce the provision of services reimbursable under a federal health care program. Relying on a 2023 [Supreme Court decision](#) concerning a statute that criminalizes the solicitation or facilitation of certain immigration violations, the charitable organization [claimed](#) that "induce," as used in the Anti-Kickback Statute, has a "specialized criminal meaning" that is limited to the encouragement of a separate, unlawful act by the recipient of the inducement. The Anti-Kickback Statute, the organization [claimed](#), should not be read to include inducements related to "innocent" or "beneficial activities" related to patient financial assistance. However, the appeals court found no textual support for these arguments and—as the federal government had argued—held that that "induce" under the Anti-Kickback Statute should be given its ordinary meaning, that is, "to lead on; to influence; to prevail on; to move by persuasion or influence."

The organization also [claimed](#) that "remuneration," for purposes of the Anti-Kickback Statute, only applied to illicit payments that corrupt medical decisionmaking. The organization [pointed to](#) the use of the terms "kickback" and "bribe" in the Anti-Kickback Statute as evidence of the kind of remuneration prohibited by the federal provision and [further asserted](#) that charitable assistance, provided only after a physician independently prescribed a covered oncology treatment, was beyond the scope of prohibited remuneration. Again, the appeals court disagreed with this argument, [explaining](#) that "remuneration" under the Anti-Kickback Statute had a broader, ordinary meaning of "payment" or "compensation."

The Fourth Circuit in *Pharmaceutical Coalition* [took](#) a different approach to analyzing the meaning of "remuneration" than one of its sister circuits. More specifically, the appeals court [observed](#) that the Anti-Kickback Statute, as amended, forbids "*any* remuneration" that induces specified conduct (emphasis added). The term "any," the appeals court [declared](#), was a "term[] of enlargement" that supported the idea that "remuneration" has an expansive, ordinary meaning of "payment or compensation," not just the examples listed in the statute. In reaching this conclusion, the Fourth Circuit disagreed with a decision cited by the organization from the U.S. Court of Appeals for the Sixth Circuit (Sixth Circuit), *United States ex rel. Martin v. Hathaway*. In that case, the Sixth Circuit [determined](#) that "any" in the Anti-Kickback Statute merely demonstrates that the statute "covers remuneration of any type (such as cash, services, goods)," but not "anything of value."

Legal Considerations for Congress

Currently, at least some PAP arrangements, particularly those serving federal health care program beneficiaries, may come under government scrutiny for potential violations of the Anti-Kickback Statute and other fraud and abuse laws. Additionally, effective in 2025, the [Inflation Reduction Act](#) generally reduces the Medicare Part D beneficiary out-of-pocket spending cap for covered prescription drugs to \$2,000 annually (adjusted for drug price inflation in later years as codified at [42 U.S.C. § 1395w-102\(b\)\(4\)\(B\)\(i\)\(VII\)](#)), leading to questions about how these changes could impact PAP assistance. Against this legal backdrop, litigation over PAPs or other forms of patient assistance may continue. In a recent case, *Vertex Pharmaceuticals v. U.S. Department of Health & Human Services*, manufacturers of a gene

editing therapy that treats serious blood disorders sought an advisory opinion from OIG about a proposed support program. The proposed program would not pay out-of-pocket expenses for the therapy covered by federal health care programs but would instead pay for fertility services to address the adverse effects of the therapy. After OIG issued an unfavorable advisory opinion regarding the program, the company sued, and the U.S. District Court for the District of Columbia concluded that that OIG's interpretation was lawful, on somewhat similar grounds as the *Pharmaceutical Coalition* case. In April 2025, the manufacturer in *Vertex Pharmaceuticals* [appealed](#) the decision to the U.S. Court of Appeals for the D.C. Circuit.

Should Congress wish to address PAP arrangements and their interplay with federal fraud and abuse laws, lawmakers could consider legislation that amends the Anti-Kickback Statute and speaks to the precise parameters under which PAPs may provide financial assistance to federal health care program beneficiaries. An example of similar legislation is the Patient Access Act from the 118th Congress ([H.R. 9184](#)), which would have created a statutory exception to the Anti-Kickback Statute for certain travel, lodging, and other incidental expenses incurred by patients when traveling to obtain administered medications.

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