

Updates in Co-Pay Assistance and Accumulators Litigation

December 1, 2022

Key Points:

- A new legal challenge to OIG on Medicare Beneficiaries' ability to receive co-pay assistance has emerged.
- The Supreme Court has been asked to review HHS's prohibition of co-pay assistance programs under the Anti-Kickback Statute.
- The patient advocacy groups' litigation challenging the 2020 HHS Final Rule permitting co-pay accumulator adjustment programs continues to progress.

Stakeholders continue the legal battle to expand the use of co-pay assistance programs. Most recently, there have been three key litigation updates outlined below:

New Legal Challenge to OIG on Medicare Beneficiaries' Ability to Legally Receive Co-Pay Relief from Charitable Organizations:

On November 9, 2022, Pharmaceutical Coalition for Patient Access (PCPA) filed suit in the United States District Court for the Eastern District of Virginia seeking declaratory judgment and injunctive relief against the United States Department of Health and Human Services (HHS), the Secretary of HHS, the Office of the Inspector General (OIG) and the Inspector General.

PCPA, a charitable organization, "developed a program that would allow lower-income Medicare patients with cancer to secure access to Medicare Part D covered drugs and other health care services they desperately need, using funding provided by drug manufacturers that have developed breakthrough and innovative drug therapies in the fight against cancer."¹

PCPA challenges an [OIG Advisory Opinion](#), which concluded that PCPA's program "if undertaken, would generate prohibited remuneration if the requisite intent were present, which would constitute grounds for the imposition of sanctions under section 1128A(a)(7) and 1128(b)(7) of the [Social Security Act]."² In contrast, OIG concluded that the proposal "would not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP."³

Contact Information

If you have any questions about designing and implementing co-pay programs, charitable foundations or about the impact of accumulators and maximizers or related strategies and programs, please contact:

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Specifically, the PCPA proposed program would, as characterized by OIG:

“[E]stablish a pathway for each Funding Manufacturer to subsidize the cost-sharing amounts owed only for their own drugs, not for the drugs of any other Funding Manufacturer.”⁴

This program design would appear to be directly contrary to the 2nd Circuit’s decision upholding HHS’s denial of a generally similar program proposed by Pfizer, which also is a single manufacturer-per-drug program. That case is now on appeal to the United States Supreme Court (see below). Of course, we do not yet know whether the Court will take up the 2nd Circuit’s decision in the Pfizer v. HHS case, but the new PCPA filing sets the stage for a potential circuit-split in the event PCPA were to prevail up to the 4th Circuit.

Among other claims invoking constitutional and administrative law, PCPA argues that their program does not violate the federal Anti-Kickback Statute (AKS), pointing to OIG’s own opinion which noted “the PCPA program is ‘agnostic’ to the treatments selected independently by a patient’s independent medical provider,” and thus cannot satisfy the requirements under the AKS.

Update on Co-Pay Litigation Regarding Medicare Beneficiaries:

As we [previously reported](#), the 2nd Circuit issued an opinion in July 2022 to uphold the United States District Court for the Southern District of New York’s findings that Pfizer’s proposed co-pay assistance program to financially assist Medicare beneficiaries for its heart treatment would violate the AKS. Pfizer [filed a petition for a writ of certiorari](#) on October 7, 2022, following the 2nd Circuit’s decision.

Pfizer argues in its petition that HHS’s “overbroad interpretation of [the AKS] outlaws a wide swath of routine, beneficial conduct in connection with federally funded healthcare,” explaining that “its proposed program would not induce improper utilization” of its breakthrough therapy. Amicus briefs filed in support of Pfizer emphasize concerns about over criminalization of health care providers and pharmaceutical companies,⁵ and the importance of being able to provide patients with affordable, life-saving treatments.⁶

The government has until December 14, 2022 to respond.

HIV+ Hepatitis Institute Litigation Update:

As we noted in our prior [client alert](#), The HIV+ Hepatitis Institute and two other patient organizations filed suit seeking declaratory and injunctive relief against the 2021 Notice of Benefit and Payment Parameters rule (“2021 NBPP”), which permits individual insurers and pharmacy benefit managers to use co-pay accumulators that exclude manufacturer-provided co-pay assistance from the annual statutory cap on cost sharing. On October 28, 2022, HHS moved to dismiss plaintiffs’ suit challenging the 2021 NBPP for lack of standing.⁷ In their filing, defendants argue that plaintiffs have failed to allege that 2021 NBPP causes any concrete, non-speculative injury to their organizational activities sufficient to give them standing to bring suit on their own behalf. Further, defendants claim that two of the plaintiffs, Diabetes Patient Advocacy Coalition and Diabetes Leadership Council, have both failed to sufficiently allege that they have identifiable members who have suffered concrete and particularized injury from the 2021 NBPP and who would therefore have individual standing.⁸ The motion

challenging standing is notable in part due to media reports that the plaintiffs in the suit are funded by pharmaceutical companies.⁹

On November 14, 2022, plaintiffs filed an opposition to defendant's motion to dismiss and later filed an amended complaint on November 18, 2022.¹⁰ The amended complaint alleges that individual plaintiffs have suffered direct financial harms from copay accumulators—specifically that they were forced to pay additional funds out of pocket.¹¹

The Takeaway

The outcome of the Pfizer, HIV+ Hepatitis Institute, and PCPA litigation against HHS, may have a significant impact on programs designed to help patients afford their medicines, including charity care, co-pay cards, and co-pay assistance programs. Of note, the just-passed Medicare Part D redesign as part of the Inflation Reduction Act will serve to significantly shift financial responsibility between Medicare, plans and manufacturers between now and 2025. This new cost-sharing environment will itself be impacted by the decisions reached in the co-pay assistance and accumulator litigation matters as manufacturers continue to explore ways to increase patient access and affordability and payors seek to minimize their costs.

¹ Complaint, Pharmaceutical Coalition for Patient Access v. U.S. et al., (E. D. Va. filed Nov. 9, 2022) (No. 3:22-cv-00714).

² U.S. Dep't of Health and Hum Servs., Office of Inspector Gen., OIG Advisory Opinion No. 22-19, 12 (issued Sept. 30, 2022).

³ *Id.* at 22; *see also* section 1128A(a)(5) of the Social Security Act.

⁴ *Id.* at 3.

⁵ See Brief for *Amicus Curiae* Pharmaceutical Research and Manufacturers of America in Support of Petitioner at 2, Pfizer Inc., v. U.S. Dep't. of Health and Hum. Servs., et al., No. 22-339 (U.S. Nov. 14, 2022).

⁶ See Brief of *Amicus Curiae* TrialCard Inc. in Support of Petitioner at 2, Pfizer Inc., v. U.S. Dep't. of Health and Hum. Servs., et al., No. 22-339 (U.S. Nov. 14, 2022).

⁷ Motion to Dismiss, HIV and Hepatitis Policy Inst. et.al., v. U.S. Dept. of Health and Human Services, et.al., (D.D.C filed Oct 28, 2022) (No. 1:22-cv-02604).

⁸ *See id.*

⁹ See <https://www.statnews.com/2022/08/30/in-a-new-lawsuit-pharma-backed-patient-groups-fight-federal-rule-around-copay-coupons/>.

¹⁰ See, e.g., Plaintiffs' Opp'n, HIV and Hepatitis Policy Inst. et.al., v. U.S. Dept. of Health and Human Services, et.al., (D.D.C filed Nov 14, 2022) (No. 1:22-cv-02604); Amended Complaint, HIV and Hepatitis Policy Inst. et.al., v. U.S. Dept. of Health and Human Services, et.al., (D.D.C filed Nov 18, 2022) (No. 1:22-cv-02604).

¹¹ Amended Complaint, HIV and Hepatitis Policy Inst. et.al., v. U.S. Dept. of Health and Human Services, et.al., (D.D.C filed Nov 18, 2022) (No. 1:22-cv-02604).

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