Health Industry Alert

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Updates in Co-Pay Assistance and Accumulators Legal Developments

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Key Points:

- Patient advocacy groups have filed suit challenging the legality of the 2020 HHS Final Rule permitting co-pay accumulator adjustment programs.
- The Second Circuit has upheld HHS' prohibition of co-pay assistance programs under the Anti-Kickback Statute.

The use of co-pay assistance programs has long been a point of contention among insurers, pharmacy benefit managers (PBMs) and pharmaceutical companies. As noted in our previous article, while insurers assert that these programs lead to an increase in drug spending, proponents highlight their benefits to low-income patients. The legal landscape for these manufacturer financial assistance programs continues to develop as courts are asked to weigh in on the legality of both co-pay assistance programs and accumulators. Most recently, there have been two key developments outlined below:

Development 1: Patient Advocacy Groups Have Filed Suit Challenging HHS' Final Rule Permitting co-pay Accumulator Adjustment Programs

In August 2022, three patient advocacy groups filed suit in the U.S. District Court for the District of Columbia seeking declaratory and injunctive relief against the 2021 Notice of Benefit and Payment Parameters rule ("2021 NBPP") permitting 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.

Effective in 2020, the 2021 NBPP removed a previous limitation that permitted co-pay accumulator programs only with respect to branded prescriptions where generics were available. Under the final rule, insurers are now permitted to determine whether the definition of cost sharing includes or excludes manufacturer co-pay assistance.[1] In their complaint, the HIV+Hepatitis Policy Institute, the Diabetes Leadership Council and the Diabetes Patient Advocacy Coalition assert that the 2021 NBPP violates the Affordable Care Act (ACA) and directly conflicts with the agencies' existing regulations. Pointing to the statutory text, the groups argue that, as defined, cost sharing does not

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consider where the funds for the co-payment originates, "but simply [looks to] whether the insurer require[s] the insured individual to come up with the money somewhere before the insurer will pay for the remainder of the treatment."[2] Additionally, the groups argue that interpreting cost sharing to "simultaneously" include and exclude manufacturers' funds for the benefit of insured individuals "is contrary both to the fundamental principles of interpretation and to the rule of law itself."[3]

The groups claim that the use of co-pay accumulator programs have increased since the 2021 NBPP was issued, resulting in increased health costs and diminished patient care.

The agencies have yet to file an answer.

Development 2: HHS' Prohibition of Manufacturer co-pay Assistance for Government-Insured Patients Was Upheld by the Second Circuit

On July 25, 2022, the Second Circuit upheld a lower court's findings that Pfizer's proposed co-pay assistance program to financially assist Medicare beneficiaries for its high-cost heart treatment would violate the federal Anti-Kickback Statute (AKS). Pointing to the statutory text, Pfizer argued that liability under the AKS requires an element of corrupt intent. Pfizer asserted that "any remuneration…to induce" naturally implies a quid pro quo "designed to corrupt the recipient's behavior."[4] The panel disagreed, finding that a quid pro quo transaction is not necessarily corrupt and that "to gain influence" over a person's judgment or reason "is simply the definition of persuade," which has a neutral connotation.[5]

Further, the Circuit court was "unpersuaded" by Pfizer's argument that the agency's interpretation of the AKS would criminalize beneficial activities leading to an "absurd and unjust result."[6] The panel emphasized that violations under the AKS require an intent to induce the purchase of a "federally reimbursable healthcare product." Thus, it is unlikely that Pfizer's proposed hypothetical (e.g., a "generous family member" providing financial assistance for a patient's treatment) would meet the requisite *mens rea* in violation of the statute.[7]

The Takeaway

The Department of Health and Human Services' (HHS') prohibition of pharmaceutical co-pay assistance for Medicare beneficiaries has been upheld by the Second Circuit. Meanwhile, litigation challenging the use of co-pay accumulator programs continues to emerge. As various stakeholders fight to expand the use of co-pay assistance programs, we also see courts limiting their scope. We can expect the outcomes of these lawsuits to shape the current landscape of co-pay subsidy programs.

[1] 2021 NBPP, 85 Fed. Reg. at 29,234.

[2] Complaint, HIV and Hepatitis Policy Inst. et. al., v. U.S. Dept. of Health and Human Services, et. al., (D.D.C. filed Aug 30, 2022) (No. 1:22-cv-02604) (internal quotations omitted).

[3] *Id*. at 18.

[4] Brief for Pfizer, Pfizer v. US Dept. of Health & Human Services, Case 21-2764, Dec. 17, 2021.

[5] Pfizer, Inc. v. United States HHS, 42 F.4th 67, 76 (2d Cir. 2022) (internal quotation omitted).

[6] *Id*. at 79.

[7] *Id*.