



PRESS RELEASE

Patient Groups Reply to Government’s Brief in Landmark Lawsuit Challenging Copay Accumulators

WASHINGTON (May 1, 2023) – Today, the [HIV+Hepatitis Policy Institute](#), [Diabetes Leadership Council](#), [Diabetes Patient Advocacy Coalition](#), and three patients filed [their reply](#) in support of their motion for summary judgment in the U.S. District Court for the District of Columbia in their ongoing lawsuit against copay accumulators.

The suit challenges HHS’s [2021 Notice of Benefit and Payment Parameters](#) rule, which permits insurance plans to refuse to credit copay assistance from drug manufacturers toward beneficiaries’ deductibles and out-of-pocket maximums.

In defending the rule allowing copay accumulators, [HHS claims](#) that the federal government did not actually do *anything* when it issued the 2021 NBPP on copay accumulators. Even though the rule amended the regulation to explicitly allow accumulators, the federal government contends that since manufacturer copay assistance amounts “*are not required to be . . . counted*,” the agency’s action is *actually* a “decision *not* to set definitive standards in this area.” As a result, HHS argues that not only is this lawsuit not justiciable but the challenges should fail on the merits as well.

In their reply, the patient groups argue that the federal government’s claim is meritless. Under a previous rule, any insurer that refused to credit copay assistance toward patients’ cost-sharing obligations when there was no generic alternative available was in violation of federal law. The 2021 NBPP eliminated this regulation. The plaintiffs thus contend that the rule clearly set a new legal standard for copay assistance.

“Copay accumulator programs are manifestly unlawful and endanger millions of people living with HIV, hepatitis, and other chronic conditions who rely on copay assistance to afford their medicines,” said **Carl Schmid, executive director of the HIV+Hepatitis Policy Institute**. “Instead of engaging the substance of our case, the government is making the bizarre claim that the rule which expressly allows copay accumulators did not materially change the status quo.”

The plaintiffs argue that the 2021 NBPP violates the Affordable Care Act’s limits on cost-sharing by allowing insurers to collect more money from patients than they are legally permitted. They also contend that the rule is arbitrary and capricious.

Copay accumulator adjustment programs have proliferated in recent years. According to a recent *Drug Channels* analysis, the programs were available or implemented in commercial plan designs for 89% of covered lives in 2022—up from 44% in 2018.

“As long as a patient is meeting his or her cost-sharing obligations, it shouldn’t matter where the funds are coming from,” said George Huntley, CEO of the Diabetes Leadership Council and the Diabetes Patient Advocacy Coalition. “It’s especially troubling that HHS continues to defend insurers and pharmacy benefit managers’ abusive practices when one-quarter of Americans—including many with diabetes—are struggling to afford their medications.

“By exposing the weakness of the federal government’s case, we hope to secure a ruling that delivers justice for millions of patients nationwide,” Huntley said.

The federal government has thus far refused to reverse the 2021 NBPP. But 17 states and Puerto Rico have passed laws requiring insurance plans to count copay assistance toward patients’ out-of-pocket obligations. Similar bills have been introduced in both chambers of Congress.

The government is expected to file its final brief by May 22, and oral arguments, if requested by the judge, would occur after that.

Paul Hughes of McDermott Will & Emery LLP represents the three patient groups as well as the individual patient plaintiffs.

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Helpful Links to Litigation Materials

- [Plaintiffs’ reply in support of their motion for summary judgment](#) (May 1, 2023)
- [Amicus brief -- Aired Alliance-- Aired Alliance & 28 Patient Groups](#)
- [All Briefs & Filings](#)

About the HIV+Hepatitis Policy Institute

The HIV+Hepatitis Policy Institute is a national, non-profit organization whose mission is to promote quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions.

About the Diabetes Leadership Council

The Diabetes Leadership Council is a 501(c)(3) patient advocacy organization comprised of individuals with decades of diabetes experience and leadership to advance patients-first policies at the local, state and national levels. We are people with diabetes, parents of children with diabetes, allies and tireless volunteers dedicated to improving the lives of all people impacted by this condition. Our members—all former leaders of national diabetes organizations—engage policymakers, and public and private sector influencers to call attention to the diabetes epidemic and provide a voice for 37 million Americans living with diabetes.

About the Diabetes Patient Advocacy Coalition

The Diabetes Patient Advocacy Coalition (DPAC), a 501(c)4 organization, is a grassroots alliance of thousands of people with diabetes, caregivers, patient advocates, health professionals, disease organizations and companies working collaboratively to promote and support public policy initiatives to improve the health of people with diabetes.

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