

U.S. Government Appeals Drug Copay Assistance Court Ruling *Informs Court It Will Defy Ruling & Not Enforce Victory for Patients*

WASHINGTON (November 28, 2023) – On September 29, 2023, the U.S. District Court for the District of Columbia issued a [clear ruling](#): It vacated the HHS *Notice of Benefit and Payment Parameters for 2021*, meaning that the predecessor rule pertaining to copay assistance is now in effect. And under that prior rule, health insurers must count drug manufacturer copay assistance towards a beneficiary’s out-of-pocket costs in most instances.

The Biden administration, however, has taken two separate steps to undermine this ruling. First, in an unusual “motion to clarify,” the government [announced](#) that it categorically will not enforce the Court’s ruling. Second, the government has filed an [appeal](#) with the United States Court of Appeals for the D.C. Circuit.

“We can’t comprehend why the Biden administration, which has championed access and affordability of prescription drugs for the American people, would appeal this decision. By siding against patients who depend on prescription drugs and with insurers, they are allowing insurers to ‘double bill’ and extract more money from patients and drug manufacturers by implementing copay accumulators.” said **Carl Schmid, executive director** of the **HIV+Hepatitis Policy Institute**, one of the plaintiffs in the lawsuit. “The court’s decision is very clear: copay assistance for prescription drugs without a generic equivalent must now count for patients.”

“We will vigorously defend the Court’s decision and oppose the government’s desire to disregard the Court’s ruling,” said **George Huntley, CEO** of additional plaintiffs the **Diabetes Leadership Council** and the **Diabetes Patient Advocacy Coalition**. “The federal government does not have a choice to decide for itself if it will or will not enforce a federal Court ruling. We are confident the Court will side with patients, which will dramatically help reduce their costs of prescription drugs.”

Judge John D. Bates of the U.S. District Court for the District of Columbia sided with the plaintiffs and [struck down](#) the 2021 *Notice of Benefit and Payment Parameters* rule that allowed insurers to decide whether copay assistance can count or not. He ruled that it was arbitrary and capricious because it allows insurers to decide for themselves whether copay assistance is included in the definition of “cost-sharing” based on contradictory interpretations of the same law and regulations.

Under the Administrative Procedures Act, the predecessor 2020 *Notice of Benefit and Payment Parameters* rule is now in effect and must be enforced. That rule allows copay accumulators only for brand name drugs with a generic equivalent.

Due to high deductibles and high cost-sharing, sometimes as high as 50 percent of the list price of the drug, patients depend on copay assistance to afford their drugs. [According to IQVIA](#), the amount of copay assistance totaled nearly \$19 billion last year.

Insurers and PBMs have increasingly implemented copay accumulators, a policy that allows them to collect the copay assistance but not count it towards a beneficiary's out-of-pocket costs. The Court agreed with the patient community and confirmed that copay accumulators increase patients' costs while simultaneously enhancing insurer profits.

The plaintiffs will oppose the government's position that it can disregard the Court's ruling. And they will vigorously defend the appeal. Plaintiffs, which also include three patients, will continue to be represented by Paul Hughes and Andrew Lyonsberg of McDermott Will & Emery LLP.

A link to the U.S. Government's "Appeal" can be found [here](#), and the "Motion to Clarify" can be found [here](#).

The final order issued September 29, 2023 can be found [here](#).

All briefs associated with the case can be found [here](#).

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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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