

Court Strikes Down HHS Rule that Allowed Insurers to Not Count Copay Assistance

Copay Assistance for Drugs Must Now Count in Most Instances

WASHINGTON (October 2, 2023) – In a major victory for patients who depend on prescription drugs, Judge John D. Bates of the U.S. District Court for the District of Columbia [struck down](#) a Trump administration federal rule that allowed health insurers to not count drug manufacturer copay assistance towards a beneficiary’s out-of-pocket costs.

The [case](#) was brought against the U.S. Department of Health and Human Services by the [HIV+Hepatitis Policy Institute](#), [Diabetes Leadership Council](#), [Diabetes Patient Advocacy Coalition](#), and three patients who depend on copay assistance and whose insurers implemented “copay accumulator” policies.

By using “copay accumulators,” health insurers pocket copay assistance patients receive, rather than allowing it to assist patients in paying for their necessary medication. The 2021 *Notice of Benefit and Payment Parameters* rule, promulgated during the Trump administration, authorized these practices. In its decision, the Court struck down that rule, recognizing that it is unlawful.

Insurers will now have to abide by the federal rule that governed 2020 health plans. Under that rule, copay accumulators are permissible only for branded drugs that have a generic equivalent, if allowed by state law. Now, insurers are precluded by federal regulation from implementing copay accumulators for drugs that lack generic equivalents.

“We are thrilled that the Court has taken the side of patients who have been struggling to afford their prescription drugs due to the greedy actions of insurers and their PBMs,” said **Carl Schmid, executive director** of the **HIV+Hepatitis Policy Institute**. “We call on the Biden administration and states to immediately enforce this decision and not take any further steps to undermine the copay assistance that allows patients to access their essential medications.”

“While this victory will certainly help millions of patients, it is a shame that so many have been forced to pay thousands of dollars in extra costs each year for their prescription drugs forcing us to take this legal action,” said **George Huntley, CEO** of the **Diabetes Leadership Council** and the **Diabetes Patient Advocacy Coalition**. “It is imperative that the Biden administration now support the American people by precluding big insurers and their PBMs from denying patients the benefit of all forms of support they receive in paying for their critical medicines.”

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.

At the same time, insurers and PBMs have increasingly implemented copay accumulators that have greatly impacted patients who need high-cost prescription drugs, such as those with HIV, hepatitis, cancer, arthritis, diabetes, and multiple sclerosis. In a [recent survey of commercial plans](#), 83 percent of beneficiaries are enrolled in plans that employ copay accumulators.

Despite the health insurers' claims, the Court clearly explained that copay accumulators increase patients' costs while simultaneously enhancing insurer profits. The Court dismissed health insurers' claims, echoed by the government, that drug company copay assistance translates into a reduction in how much an enrollee pays for the drug.

The Court agreed with the plaintiffs that the rule 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.

The Court repeatedly rejected the government's arguments and agreed that, based on the arguments the plaintiffs presented, copay assistance would be required to be included as part of "cost-sharing" since the regulation states that cost-sharing is "any expenditure required by or on behalf of an enrollee." The Court ultimately remanded to HHS in the event the agency wishes to offer further views as to the legality of copay accumulators under the ACA.

The plaintiffs are thankful to the 29 patient groups that jointly submitted [an amicus brief](#). They are also grateful to Paul Hughes and Andrew Lyonsberg of McDermott Will & Emery LLP for representing them.

A link to the Court's opinion can be found [here](#) while the final order 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.

Media Contacts:

Greta Timmins
(202) 796-5015
greta@keybridge.biz

Durin Hendricks
DLC@nahigianstrategies.com

Jennifer Burke
jburke@hivhep.org
(301) 801-9847