

Court Makes It Clear: Rule Requiring Copay Assistance to Count Now in Effect

Clarification Sought by U.S. Government Decided in Favor of Patient Groups

WASHINGTON (December 26, 2023) – The U.S. District Court for the District of Columbia handed down another victory to patient groups who challenged the U.S. government’s rule allowing insurers to not count prescription drug copay assistance towards a beneficiary’s out-of-pocket costs. On December 22, 2023, Judge John D. Bates explained that his earlier [decision](#) in favor of the patient groups means that the prior rule is now in effect. That rule requires copay assistance to count as patient cost-sharing for prescription drugs, except for brand name drugs with a generic equivalent.

Despite the earlier clear victory, HHS took an unusual step and sought clarification from the Court questioning what rule is now in effect. After hearing from both sides, the Court quickly announced its decision.

The Court’s [opinion](#) states in the plainest of terms: “The prior (and thus reinstated) rule is the ‘2020 NBPP’.”

The “2020 NBPP” is the 2020 *Notice of Benefit and Payment Parameters Rule* which permitted manufacturer assistance to be excluded from cost-sharing only for “specific prescription brand drugs that have an available and medically appropriate generic equivalent.” The preamble to that rule explained that “[w]here there is no generic equivalent available or medically appropriate . . . amounts paid toward cost sharing using any form of direct support offered by drug manufacturers *must be counted* toward the annual limitation on cost sharing.”

To the extent that HHS asserted it will not enforce the 2020 NBPP—a conclusion plaintiffs challenge as unlawful—the Court declined HHS’ request to validate its point of view. Rather, the Court did not opine on whether HHS can maintain a blanket non-enforcement position since it was never an issue raised in the case and would go beyond a simple clarification of the Court’s ruling.

Regardless of HHS enforcement, copay accumulators are now broadly unlawful, a legal restriction which is generally enforceable by state insurance commissioners and plan holders themselves, via ERISA and other actions.

“We thank the Court for siding, yet again, with patients who struggle to afford their prescription drugs and rely on copay assistance,” said **Carl Schmid, executive director** of the **HIV+Hepatitis Policy Institute**, one of the plaintiffs in the lawsuit. “The Court has clarified what we have been asserting: the rule that states copay assistance must count is in effect. Now, that clear rule must be followed by insurers.”

“The government cannot simply ignore the fact that the rule allowing insurers to implement copay accumulators has fallen. It has been vacated,” said **George Huntley, CEO** of additional plaintiffs the **Diabetes Leadership Council** and the **Diabetes Patient Advocacy Coalition**. “We, again, call on the federal government to issue guidance that copay assistance, in most instances, must count. Insurers must follow the law, and state and all other regulators must ensure that insurers do not implement copay accumulators.”

In addition to seeking the “Motion to Clarify,” the Biden administration filed an [appeal](#) with the United States Court of Appeals for the D.C. Circuit. Separately, the patient groups, along with the three impacted patients who are part of the litigation, filed a separate protective [appeal](#). While these appeals are pending, the 2020 *Notice of Benefits and Payment Parameters* rule is in effect.

Plaintiffs’ representatives in the case are Paul Hughes and Andrew Lyonsberg of McDermott Will & Emery LLP.

The Motion to Clarify opinion and order issued on December 22, 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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