

Patient Groups Explain to the Court Why Copay Assistance Ruling Must Be Enforced Now

Also, File Appeal of District Court's Ruling

WASHINGTON (December 12, 2023) – Patient groups, after successfully challenging the U.S. government’s rule allowing insurers to not count prescription drug copay assistance towards patient cost-sharing, filed a [brief](#) yesterday explaining why the government must enforce the Court ruling. Additionally, the [HIV+Hepatitis Policy Institute](#), [Diabetes Leadership Council](#), [Diabetes Patient Advocacy Coalition](#), and three impacted patients filed their own [appeal](#) of the U.S. District Court [ruling](#) to the U.S. Court of Appeals for the D.C. Circuit.

The government recently filed a “Motion for Clarification” in which they declared their intent to not enforce the Court’s ruling. In response the patient groups wrote, “Now, after losing on the merits, the government takes an extraordinary position and, under the guise of requesting ‘clarification,’ asks the Court to sanction its behavior. The Court should explicitly reject the government’s request.” The brief continues, “That course of conduct is unlawful, and the Court should not sanction it.”

In the brief, the groups explained that since the rule allowing insurers to decide whether copay assistance counts was stricken, the previous version of the regulation “under well-established doctrine was returned to force.” That rule requires copay assistance to count toward patient cost-sharing for brand name drugs without a generic equivalent. The patient groups’ brief even quoted an AHIP official who testified in Ohio recently that the prior version of the rule is now in force.

“We continue to be astonished by the government’s continued siding with big insurers and the length they are going to allow them to make money off of copay assistance that is meant for patients to help pay for their essential prescription drugs,” said **Carl Schmid, executive director** of the **HIV+Hepatitis Policy Institute**. “First, they defended insurers in court to allow them to implement copay accumulators and now, even after losing, they are refusing to enforce the Court’s decision.”

“While we remain baffled by the Biden administration’s actions in this case, we look forward to a quick positive ruling from the Court and the relief it will provide to patients in affording their prescription drugs,” said **George Huntley, CEO** of the **Diabetes Leadership Council** and the **Diabetes Patient Advocacy Coalition**. “We and the entire patient community urge the Biden administration to ensure copay assistance counts for patients.”

Support for these positions has been echoed by a bipartisan group of members of Congress. Yesterday, Reps. Earl L. “Buddy” Carter (R-GA), Nanette Diaz Barragán (D-CA), and Mariannette Miller-Meeks (R-IA) sent a [letter](#) to the Biden administration signed by 48 representatives to voice their disappointment in the government’s recent legal challenges regarding copay accumulators.

They wrote, “We believe it would be beneficial to our constituents if a notice was quickly issued reaffirming the 2020 NBPP final rule that group health plans and health insurance issuers must count copay assistance toward the patient’s [maximum annual limitation on cost sharing (MOOP)] for drugs that do not have a medically appropriate generic equivalent available.”

The members continue: “We believe [copay accumulator adjustment programs (AAPs)] permit health plans, PBMs, or third parties to profit from copay assistance undermining the intended impact of this type of assistance, which helps eligible patients afford their out-of-pocket costs at the pharmacy counter and can significantly improve patient adherence to medicines.”

Plaintiffs are represented by Paul Hughes and Andrew Lyonsberg of McDermott Will & Emery LLP.

A link to the patient groups’ “Response to the Government’s Motion for Clarification” can be found [here](#), and the “Notice of Appeal” can be found [here](#).

It is expected that the U.S. government will submit a response to the reply brief by December 18, 2023.

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

###

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
media@diabetesleadership.org

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