

Patient Groups File Suit to End Policy That Prohibits Copay Assistance from Counting Toward Patients' Out-of-Pocket Spending

Harmful Insurer & PBM Policy Increases Prescription Drug Costs for Patients

WASHINGTON (August 30, 2022) – Today, the <u>HIV+Hepatitis Policy Institute</u>, the <u>Diabetes Leadership Council</u> (DLC), and the <u>Diabetes Patient Advocacy Coalition</u> (DPAC), representing 42 million people, <u>filed suit</u> in the U.S. District Court for the District of Columbia challenging a federal rule that allows health insurers to avoid counting the value of drug manufacturer copay assistance toward patients' out-of-pocket cost obligations.

Due to increasing deductibles and cost-sharing requirements, patients often rely on copay assistance to help them afford their prescriptions. However, in recent years, insurers and pharmacy benefit managers have instituted harmful policies that do not apply the assistance toward beneficiaries' out-of-pocket costs and deductibles. These policies, which significantly increase patients' costs, are often referred to as "copay accumulator adjustment programs."

These programs allow the insurer to divert the benefit of the assistance away from the patient to the plan then make the patient pay that amount again before meeting their deductible and other out-of-pocket cost obligations.

The U.S. Department of Health and Human Services' <u>2021 Notice of Benefit and Payment Parameters rule</u>, promulgated under the Trump administration, allows insurers to implement these programs. The complaint filed today challenges the legality of the rule under the Administrative Procedures Act and contends the rule is arbitrary and capricious.

The complaint asserts that the HHS rule violates federal law and directly contradicts the government's own definition of cost-sharing. The Affordable Care Act (ACA) sets cost-sharing caps, and the patient groups contend the current rule allows insurers to "double dip" and receive payments in excess of the amount to which they are legally entitled. The ACA defines cost-sharing as "deductibles, coinsurance, copayments, or similar charges; and *any other expenditure required of an insured individual* which is a qualified medical expense." Additionally, federal regulations define cost-sharing as "any expenditure required by or *on behalf of* an enrollee with respect to essential health benefits," including deductibles, coinsurance, copayments, or similar charges. Therefore, it should not matter whether the assistance comes from a friend, charity, or drug manufacturer.

According to the patient groups' complaint, the HHS rule is arbitrary and capricious for several reasons, including that HHS allows insurers to decide how to interpret cost-sharing in two conflicting ways—to either include or exclude copay assistance from cost-sharing calculations. Without explanation, HHS also abandoned its previous rule that copay assistance must count

toward beneficiaries' out-of-pocket cost obligations, except for brand name drugs that have a generic equivalent.

"This practice is not only illegal but increases the cost of prescription drugs for millions of patients nationwide," said **Carl Schmid, executive director of the HIV+Hepatitis Policy Institute.** "Nearly one in four Americans taking prescription drugs struggles to afford them. The growing practice of insurers and PBMs not counting copay assistance is one reason why. We trust the court will side with us—and invalidate the ability to implement these punitive practices that impact people with HIV, hepatitis, and so many other health conditions that are treated with prescription drugs."

"People today are struggling with an ever-increasing cost of living, including prescription drugs. On behalf of patients with diabetes who depend on copay assistance, we must end this cruel practice orchestrated by health insurers and PBMs," commented **George Huntley, Chief Executive Officer of DLC and DPAC**. "As we urge HHS to reverse the rule, we continue to work at the federal and state levels to pass laws outlawing this practice. While we have been successful in 14 states and Puerto Rico, helping millions of patients in those jurisdictions, we need to end copay accumulator programs nationally. Success with this claim will do that."

The three patient groups are being represented by McDermott Will & Emery LLP.

A link to the complaint can be found <u>here</u>.

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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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