



March 12, 2024

Re: Request for Prompt Enforcement of Prescription Drug Copay Assistance Court Ruling

Dear Commissioner:

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. We have long advocated for affordable access to healthcare, including prescription medications. A recent United States District Court for the District of Columbia ruling pertaining to copay assistance will dramatically help patients afford their medications.

We write to urge you to immediately enforce this decision and the rule that it reinstated, issue a bulletin advising insurers that they are obligated to comply with the reinstated rule, and take necessary enforcement actions against insurers that are not in compliance.

Need for Copay Assistance

Many patients need copay assistance in order to afford their prescription drugs. The significant patient need is a function of high cost-sharing obligations, often in the form of coinsurance based on the list price of a drug, and high deductibles.

In 2022, according to IQVIA, patient out-of-pocket costs in 2022 were \$82 billion for prescription drugs. That was an increase of \$3 billion from 2021. Manufacturer copay assistance reduced these large patient costs by nearly \$19 billion and accounted for 23 percent of the out-of-pocket costs.¹

Without this kind of assistance, patients never would be able to start or would abandon the drugs they need to keep them healthy and alive. According to an IQVIA analysis, an estimated 92 million prescriptions were abandoned at the pharmacy in 2022 (up from 81 million in 2021), with the abandonment rate over one in three for prescriptions above \$75 and up to \$250 in out-of-pocket costs. More than half of all prescriptions with a cost above \$250 are never picked up by patients.²

¹ “The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026,” IQVIA Institute, April 2022, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf>, at 40.

² Id. at 47.

Copay Accumulator Adjustment Programs

Accumulator adjustment programs prevent copayment assistance available for patients dependent on brand name specialty drugs used to treat chronic illnesses, rare diseases, and other disabling health conditions. These programs prevent copayment assistance from counting toward a patient's deductible, coinsurance, and maximum out-of-pocket obligations. Even though insurers are collecting assistance from drug makers, those sums are not "counted" by the patient's insurance company, leaving the patient unable to pay for their treatment when the manufacturer assistance ends or the patient attempts to access other healthcare items or services.³

Because these programs are often not disclosed at all, deceptively hidden, or described in a confusing or unclear manner, many patients subject to accumulators and maximizers are surprised to learn that they have not satisfied their deductibles and out-of-pocket maximum. Then, the surprised patients are unable to pay patient obligations for needed healthcare, and, as a consequence, they fail to access medically necessary care. The result is that their health and, sometimes, their very lives are put at risk.

The Federal Regulations

The federal regulations have, since they were issued in 2012, required that plans recognize cost-sharing payments made "by or on behalf of" a patient.⁴ "Cost sharing" is defined, in relevant part, as "any expenditure required by or on behalf of an enrollee" where "such term includes deductibles, coinsurance, copayments or similar charges."⁵ That broad definition then feeds into the regulation's obligation that both "self-only coverage" and "other ... coverage" ensure that "cost sharing may not exceed" the listed "annual dollar limit[s]."⁶

After the patient community began raising concerns about unfair and costly accumulator policies, the federal government included in the 2020 Notice of Benefits and Payment Parameters Rule a provision that confirmed that accumulators are unlawful. The federal agency was clear. As the preamble stated, "the final regulation limits" the ability of plans "to exclude manufacturer coupons from counting towards the annual limitation on cost sharing."

The only change that the 2020 NBPP made to the broad, pre-existing obligation for plans to recognize cost sharing was the creation of a limited exception if the drug at issue had a medically appropriate generic equivalent. Specifically, "[n]otwithstanding" the broad requirement to recognize cost sharing reflected in Section 156.130(a), the regulation permitted "cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers" to be excluded by plans, if they choose, but only where a "medically

³ Maximizers are similar programs, which increase co-payment obligations to very high levels in an effort to draw out the highest level of assistance that a manufacturer will offer to a patient. Patients, again, may ultimately pay amounts far in excess of the out-of-pocket maximum under these programs.

⁴ Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified health Plans; Exchange for Employers, 77 Fed. Reg. 18310, 18445 (Mar. 27, 2012).

⁵ 45 C.F.R. Section 155.20.

⁶ 45 C.F.R. Section 156.130(a)(1)-(2).

appropriate generic equivalent” to the drug is available.⁷ As the rule made clear, “[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.”⁸

Subsequently, the 2021 Notice of Benefit and Payment Parameters rule took the position that an insurer could implement an accumulator, if it choose to do so, without regard to whether the drug therapy in question had a generic equivalent.⁹ That rule was based, in part, on the assumption that, even with this latitude, insurers would not, in fact, implement these programs in a significant manner.¹⁰

That premise proved terribly wrong. Accumulators and maximizers were dramatically expanded after the 2021 NBPP became effective.¹¹

The U.S. District Court Case and Judgment

The **HIV + Hepatitis Policy Institute**, along with the Diabetes Leadership Council, Diabetes Patient Advocacy Coalition, and three affected patients, filed suit against the U.S. Department of Health and Human Services seeking a declaratory judgment that the 2021 NBPP was unlawful. The District Court, in a decision issued on September 29, 2023, now more than five months ago, “set aside the 2021 NBPP” based on “its contradictory reading of the same statutory and regulatory language,” among other reasons.¹² In deciding the case, the court expressed concerns that accumulators increased patient costs.

Following the issuance of summary judgment to plaintiffs in the case, defendants filed a motion seeking clarification of that judgment. The court held, in response, that “[t]he effect of vacatur is to ‘reinstate the rules previously in force’” and that [t]he prior (and thus reinstated) rule is the ‘2020 NBPP.’”¹³ Accordingly, under 2020 NBPP rule that applies by virtue of the court’s vacatur of the 2021 rule, an insurer is required to recognize deductible, copayment, coinsurance, and other payments made by or on behalf of a patient, unless the drug at issue has a generic equivalent.

⁷ 42 C.F.R. Section 156.130(h).

⁸ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020, 84 Fed. Reg. 17454, 17545 (Apr. 25, 2019).

⁹ Patient and Affordability Act; HHS notice of Benefit and Payment Parameters for 2021, 85 Fed. Reg. 29164, 29261 (May 14, 2020).

¹⁰ Id. at 29232.

¹¹ The AIDS Institute, “Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness” (March 2024) (available at <https://aidsinstitute.net/documents/TAI-2024-Report-2.27.pdf>).

¹² *HIV and Hepatitis Policy Institute v. U.S. Department of Health and Human Services*, Memorandum Opinion, CA22-2604 (JDB) (D.D.C. Sept. 29, 2023).

¹³ *HIV and Hepatitis Policy Institute v. U.S. Department of Health and Human Services*, Memorandum Opinion, CA22-2604 (JDB) (D.D.C. Dec. 23, 2023).

Insurers Actions After the Judgment

In the five months since the District Court ruled, unfortunately, we are finding that insurers have not changed their practices to bring them into compliance with the 2020 NBPP. In fact, patients continue to report that they are subject to and are being financially harmed by accumulators and maximizers.

Their struggles are documented in the most recent report on accumulators from The AIDS Institute.¹⁴ That report details, on a state-by-state basis, the disturbing prevalence of copay accumulator adjustment policies in ACA marketplace plans in 2024, notwithstanding the legal effect of the District Court's judgment. Further, a number of insurers have told their impacted beneficiaries that they will not enforce the court ruling unless regulators direct them to do so or legal action is taken against them.

Given the known, harmful impact on patients of these programs, including the discontinuation of life-saving therapies, we urge you to act to ensure insurers in your state are in compliance with the law. We ask that you issue a bulletin to insurers and take appropriate enforcement action against those insurers that are in violation of their obligations. Nineteen states, Puerto Rico, and the District of Columbia have already banned these practices by state law, and we continue to urge you to support state and federal legislation to end these deceptive and cruel practices.

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We are available at your convenience to discuss these requests with your office and would be pleased to suggest draft language for a bulletin. Thank you for everything you do on behalf of patients to ensure that they are treated fairly and are protected from abusive practices. I look forward to seeing you at the NAIC meeting in Phoenix. If you have any questions, please feel free to reach out to me at cschmid@hivhep.org or (202) 365-7725.

Thank you very much.

Sincerely,



Carl E. Schmid II
Executive Director

¹⁴ AIDS Institute, "Unchecked: Copay Accumulator Adjustment Policies in 2024" (Feb. 2024) (available at <https://www.theaidsinstitute.org/copays/TAI-copay-report-2024>).