

# Congress of the United States

Washington, DC 20510

December 11, 2023

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

The Honorable Julie Su  
Acting Secretary  
Department of Labor  
200 Constitution Avenue NW  
Washington, DC 20210

The Honorable Janet Yellen  
Secretary  
U.S. Department of the Treasury  
1500 Pennsylvania Avenue N.W.  
Washington, D.C. 20220

Dear Secretary Becerra, and Acting Secretary Su, and Secretary Yellen:

We are writing regarding the recent decision from the U.S. District Court for the District of Columbia that vacates the 2021 Notice of Benefit and Payment Parameters (NBPP) Final Rule provision that permitted the use of copay accumulator adjustment programs (AAPs) and remanded to the U.S. Department of Health and Human Services (HHS) to interpret the definition of “cost sharing.”<sup>1</sup> As the sponsors of the Help Ensure Lower Patient (HELP) Copays Act, which would ensure copay assistance counts toward the patient’s maximum annual limitation on cost sharing (MOOP), we are disappointed in HHS’s decision to file a notice of appeal and HHS’s intention to not take any enforcement action against health insurance issuers or health plans that fail to count copay assistance toward the patient’s MOOP. 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 MOOP for drugs that do not have a medically appropriate generic equivalent available.

We believe this decision is an important step in the right direction for patients who rely on manufacturer copay assistance to alleviate affordability and access challenges for their medicines. Comprehensive, affordable, and accessible prescription drug coverage is important to preventing, treating, and curing acute and chronic medical conditions, as well as improving quality of life and reducing spending on other health care services.<sup>2</sup>

The 2021 NBPP final rule permitted group health plans and health insurance issuers to use AAPs without limitation. AAPs permit plans and issuers to exclude the value of copay assistance from

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<sup>1</sup> HIV & Hepatitis Policy Institute et al., v. U.S. Dep’t of Health & Human Services et al., No. 1:22-cv-02604 (D.D.C. Sept. 29, 2023) available at <https://hivhep.org/wp-content/uploads/2023/09/HIV-Hepatitis-Policy-Institute-v.-HHS-DDC-opinion.pdf>.

<sup>2</sup> Congressional Budget Office. Offsetting effects of prescription drug use on Medicare’s spending for medical services. 2012. [https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets\\_One-col.pdf](https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf).

accruing toward the statutorily required annual limitation on cost sharing.<sup>3</sup> Historically, such copay assistance has counted toward the annual limitation on cost sharing under the Affordable Care Act (ACA), which helps protect enrollee access to medically necessary treatment options. We believe AAPs undermine this important patient protection under the ACA that provides patients and families with greater predictability and certainty about their maximum out-of-pocket exposure on an annual basis. Despite the view at the time that this “open door” would not necessarily lead to an increase in uptake of AAPs by health plans, issuers, and PBMs, these programs have nonetheless proliferated in the intervening years. In fact, a 2023 report by The AIDS Institute found that nearly two-thirds of individual health plans available on the ACA marketplace included AAPs.<sup>4</sup> An analysis by IQVIA revealed that across all commercial markets in 2021, 43% of covered lives were in commercial health plans that had implemented AAPs.<sup>5</sup>

We believe AAPs permit health plans, PBMs, or third parties to profit from copay assistance, undermine 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. The proliferation of these policies in recent years has led to financial hardships for patients across the country and we consistently hear from constituents who have suffered as a result. Out-of-pocket costs can reach into the thousands per dose of a specialty medication, even for insured patients, making copay assistance a critical financial lifeline for many patients living with serious chronic illness. Research from Harvard University shows that reduced cost sharing for cardiovascular medicines increased adherence and had a greater impact on reducing the risk of vascular events and medical costs among nonwhite patients.<sup>6</sup>

According to the data, the use of AAPs impacts the most vulnerable patients and prevent many from being able to access life-saving and life-changing medications. A 2021 survey showed that nearly half of respondents (46%) indicated they or a household member had not been able to afford out-of-pocket costs in the past year, and 6 in 10 said they would have extreme difficulty affording their treatments without copay assistance programs being applied to their cost sharing.<sup>7</sup> AAPs run directly counter to the Administration’s policy goals of lowering patient out-of-pocket costs for prescription drugs and taking steps to eliminate disparities in health care access and outcomes. Recent research has shown that non-white patients are 31% more likely to be exposed to an AAP than white patients.<sup>8</sup>

There is much evidence to show AAPs are having a negative impact on patients’ physical and financial health. An IQVIA survey showed that between 25-36% of respondents discontinued

<sup>3</sup> Craig B. Bleifer, Kelly M. Cleary, Nathan A. Brown, John R. Jacob, Ashish Alexander. “Co-Pay Assistance and Accumulators in the Legal Spotlight: A Changing Landscape,” June 17, 2022. Available at: <https://www.akingump.com/en/insights/alerts/co-pay-assistance-and-accumulators-in-the-legal-spotlight-a-changing-landscape-1>.

<sup>4</sup> The AIDS Institute, *Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness: Copay Accumulator Adjustment Policies in 2023*, (February 2023), [TAI-Report-Copay-Accumulator-Adjustment-Programs-2023.pdf](https://aidsinstitute.net/TAI-Report-Copay-Accumulator-Adjustment-Programs-2023.pdf) (aidsinstitute.net).

<sup>5</sup> James Brown, Rahel Ehrenberg, Ruthy Glass, Benjamin Plotnik, *Five Years and Counting: Deductible Accumulators and Copay Maximizers in 2022*, IQVIA, (2022), <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2022/five-years-and-counting-deductible-accumulators-and-copay-maximizers-in-2022.pdf>.

<sup>6</sup> Choudhry, NK., Bykov, K., Shrank, WH., et al. Eliminating medication copayments reduces disparities in cardiovascular care. *Health Affairs* 2014 33:5, 863-870. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.0654>.

<sup>7</sup> Patients & Family Caregivers: Prescription Drug Affordability Challenges During COVID-19. [chrome-extension://efaidnbmninnibpcapjpcglclefindmkaj/https://allcopayscount.org/wp-content/uploads/2022/06/NHF-National-Patients-and-Caregivers-Survey-on-Copay-Assistance-Key-Findings.pdf](https://chrome-extension://efaidnbmninnibpcapjpcglclefindmkaj/https://allcopayscount.org/wp-content/uploads/2022/06/NHF-National-Patients-and-Caregivers-Survey-on-Copay-Assistance-Key-Findings.pdf)

<sup>8</sup> Janssen Health Equity Policy Brief. How Insurers Divert Co-pay Support Meant for Patients. [https://transparencyreport.janssen.com/\\_document/janssen-caps-infographic?id=00000184-cc93-d0e5-a59c-efd3c3980000](https://transparencyreport.janssen.com/_document/janssen-caps-infographic?id=00000184-cc93-d0e5-a59c-efd3c3980000)

therapy when they received an unexpected high charge of over \$1,500 during the plan year as a result of AAPs.<sup>9</sup> For many chronic disease patients, discontinuation of therapy can lead to irreversible and in some cases life-threatening health consequences.

Accordingly, we believe that our constituents would be best served if the decision is not appealed and that patients would be protected by issuing immediate guidance to reinstate the requirement from the 2020 NBPP final rule that plans must count manufacturer copay assistance toward the annual limitation on cost sharing for drugs that do not have a medically appropriate generic equivalent available.<sup>10</sup> To date, 19 states, Puerto Rico, and Washington, D.C. have taken steps to ban or limit use of AAPs accumulator adjustment programs; however, a federal prohibition is needed to assist all commercially insured patients.<sup>11</sup> HHS itself acknowledges “situations when a patient has been subject to significant out-of-pocket costs because the patient has not progressed through the deductible phase of the health plan” due to AAPs not applying the value of the manufacturer-sponsored assistance to the patient’s deductible.<sup>12</sup> Further, HHS notes that “when this happens, the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions.”<sup>13</sup>

We believe that by vacating the 2021 NBPP final rule, the court decision revives the 2020 NBPP final rule, and therefore believe that it would be helpful to confirm the policy from the 2020 NBPP final rule to prohibit AAPs, except when a medically appropriate generic equivalent is available, so that patients with significant medical needs are shielded from high-cost sharing on necessary medications when no alternative options are available.<sup>14</sup>

Thank you for your consideration and we stand ready to work with you to ensure patients receive these cost-sharing protections.

Sincerely,

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<sup>9</sup> IQVIA. Accumulator adjustment programs can lead to increased use of copay assistance and increase the risk of patient discontinuation. November 13, 2020. <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Accumulator-adjustment-programs-from-payers-lead-to-surprise-out-of-pocket-costs-and-nonadherence.pdf>

<sup>10</sup> 84 Fed. Reg. 17454, 17568 (April 25, 2019) (codified at 45 C.F.R. § 156.130(h); version effective from June 24, 2019 to July 12, 2020) (“2020 NBPP”)

<sup>11</sup> These states include: Arizona, Arkansas, Colorado, Connecticut, Delaware, Georgia, Illinois, Kentucky, Louisiana, Maine, New Mexico, New York, North Carolina, Oklahoma, Tennessee, Texas, Virginia, Washington, and West Virginia.

<sup>12</sup> Final Rule: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS-2482-F) from the Department of Health and Human Services, Centers for Medicare & Medicaid Services. <https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and>

<sup>13</sup> Ibid.

<sup>14</sup> In fact, in the 2020 NBPP final rule, HHS reasoned “where there is no generic equivalent available or medically appropriate alternative, it is less likely that the manufacturer’s coupon would disincentivize a lower cost alternative and thereby distort the market.” 84 Fed. Reg. at 17545.



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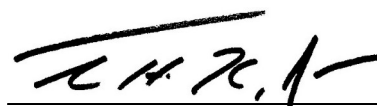
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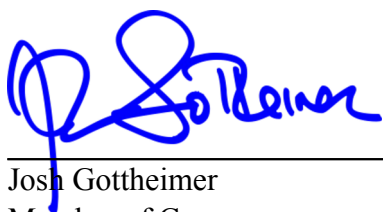
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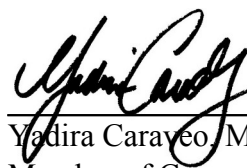
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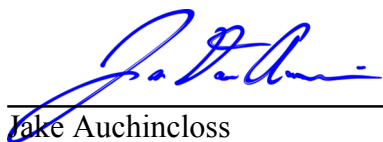
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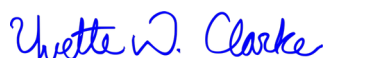
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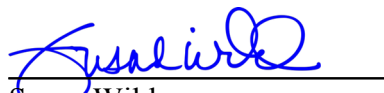
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