United States Senate
WASHINGTON, DC 20510

December 20, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

The Honorable Julie Su
Acting Secretary
U.S. Department of Labor
200 Constitution Avenue N.W.
Washington, D.C. 20210

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

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

We are writing in support of the recent decision from the U.S. District Court for the District of Columbia that vacated 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."[1] This decision is an important step in the right direction for low-income and other eligible patients who rely on manufacturer and nonprofit copay assistance programs to alleviate affordability and access challenges for their medicines. We are disappointed in HHS's decision to file a notice of appeal of the decision and HHS's articulated intention to not take any enforcement action against health insurance issuers or health plans that fail to count copay assistance toward the patient's maximum annual limitation on cost-sharing. Instead of appealing the court's ruling, we urge you to adopt policies from the 2020 NBPP that strike the right balance of preserving a plan's ability to control costs while also putting the patient first.

Patient assistance programs (PAPs) help low-income and vulnerable patients with complex conditions access life-saving medicine. Historically, these copay assistance programs counted toward the annual limitation on cost-sharing, and the policy was reaffirmed under the Affordable Care Act.[2] The patient protection on cost-sharing provided patients and families with greater predictability and certainty about their maximum out-of-pocket exposure on an annual basis. It

[1] *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), https://law.justia.com/cases/federal/district-courts/district-of-columbia/dcdce/1:2022cv02604/246787/42/.
[2] 42 U.S.C. § 18022(c)(3)

also helped improve patient adherence to their medication and overall health outcomes. For example, one study showed 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 non-white patients.[3]

In recent years, health plans, pharmacy benefit managers, and third-party administrators have used AAPs to help to control costs. However, like cost utilization management, AAPs can be used as a profit-seeking tactic. When HHS published the 2021 NBPP final rule, it permitted group health plans and health insurance issuers to use AAPs without limitation. The Administration believed this "open door" would not necessarily lead to an increased uptake of AAPs by PBMs, but they were wrong. These programs proliferated in the intervening years. Nearly two-thirds of individual health plans available on the ACA marketplace included AAPs.[4] It was also estimated that of all commercial markets in 2021, 43% of covered lives were in commercial health plans that had implemented AAPs.[5]

As a result of this policy change, patients in our home states suffered, facing financial hardship and barriers to their once-accessible life-saving medicine. In many cases, patients or their family members found out about the AAP not counting their assistance at the pharmacy counter. They were left embarrassed, anxious, and without recourse. A recent survey showed that between 25-36% of respondents discontinued therapy when they received an unexpected high charge of over $1,500 during the plan year as a result of AAPs.[6] For many chronic disease patients, discontinuation of therapy can lead to irreversible and in some cases life-threatening health consequences. Further, six in 10 said they would have extreme difficulty affording their treatments without copay assistance programs being applied to their cost-sharing.[7] Moreover, recent research has shown that non-white patients are 31% more likely to be exposed to an AAP than white patients.[8] It was for these reasons, and more, that patient groups took action against the 2021 NBPP. Patients were not the only stakeholder to respond. State regulators have passed and are in the process of passing legislation. To date, 19 states, the District of Columbia, and Puerto Rico have banned or limited the use of AAPs.[9]

As you consider next steps, we strongly encourage you to support patients by reconsidering your appeal of the court's ruling and instead adopting the 2020 NBPP policy. It required plans to

[3] Choudhry, N.K., 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.

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

[5] James Brown, Rahel Ehrenberg, Ruthy Glass, and Benjamin Plotnik, *Five Years and Counting: Deductible Accumulators and Copay Maximizers in 2022*, IQVIA White Paper, 2022, accessed October 25, 2023, https://www.iqvia.com/locations/united-states/library/white-papers/five-years-and-counting-deductible-accumulators-and-copay-maximizers-in-2022.

[6] 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/en/Blog/accumulator-adjustment-programs-lead-to-surprise-out-of-pocket-costs-and-nonadherence-analysis-finds.

[7] Patients & Family Caregivers: Prescription Drug Affordability Challenges During COVID-19. https://www.hemophilia.org/sites/default/files/document/files/NHF%20-%20National%20Patients%20and%20Caregivers%20Survey%20on%20Copay%20Assistance%20%28Key%20Findings%29.pdf

[8] 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.

[9] 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.

count manufacturer copay assistance toward the annual limitation on cost-sharing for drugs that do not have a medically appropriate generic equivalent available.[10] In the 2020 rule, HHS reasoned that it would be less likely that the manufacturer's assistance would disincentivize a lower cost alternative and thereby distort the market.[11] HHS itself acknowledged 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.[12] HHS further noted 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."[13]

We also strongly believe that federal legislative action is also needed to restore this vital patient protection. In fact, Congress is currently working on a bipartisan, bicameral basis to advance legislation to ensure copay assistance counts toward the patient's maximum annual limitation on cost-sharing.[14]

Thank you for your consideration of this request. We look forward to your reply and your plan to ensure patients receive cost-sharing protections.

Sincerely,

Tim Kaine
United States Senator

Roger Marshall, M.D.
United States Senator

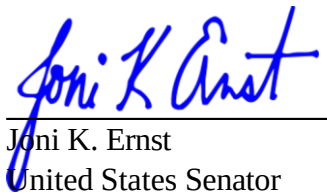
[10] 84 Fed. Reg. 17454, 17568 (April 25, 2019) (codified at 45 C.F.R. § 156.130(h); version effective from June 24, 2019 to July 12, 2020) ("2020 NBPP")

[11] 84 Fed. Reg. 17454.

[12] 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, accessed October 25, 2023, https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and.

[13] *Ibid.*

[14] Help Ensure Lower Patient (HELP) Copays Act, S. 1375, 118th Congress, (2023), https://www.congress.gov/bill/118th-congress/senate-bill/1375; Help Ensure Lower Patient (HELP) Copays Act, H.R. 830, 118th Congress, (2023), https://www.congress.gov/bill/118th-congress/house-bill/830.



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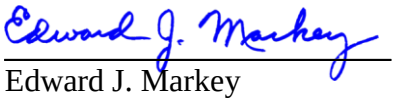
United States Senator



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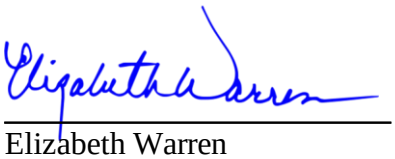

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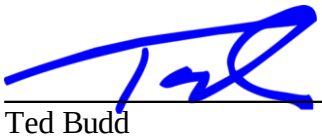

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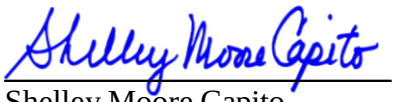

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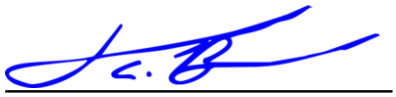

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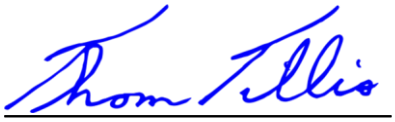

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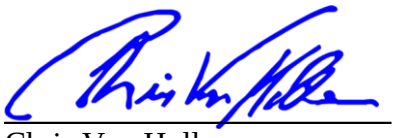

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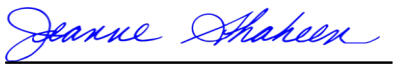

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