

May 25, 2022

The Honorable Lina Kahn
Chairwoman
Federal Trade Commission
600 Pennsylvania Ave NW
Washington, DC 20580

Re: FTC-2022-0015-0001 Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and their Impact on Independent Pharmacies and Consumers

Dear Chairwoman Kahn:

On behalf of the undersigned members of the All Copays Count Coalition, we are pleased to offer comments on the impact of pharmacy benefit manager (PBM) practices on consumers. The All Copays Count Coalition is comprised of patient, consumer, and provider organizations dedicated to ensuring that copay assistance patients rely on to afford their medications counts towards their cost-sharing. Over the last few years, the ability of patients to use copay assistance to help them pay afford their medications has been increasingly threatened by a practice employed by PBMs called accumulator adjustment programs, which prohibit copay assistance from counting towards a patient's deductible or out-of-pocket maximum. These practices jeopardize patients' access to medications and their ability to remain adherent to their treatment protocol. These practices represent a further distortion of the rebate system in which patients get caught in the middle and ultimately bear and suffer the consequences.

Copay assistance is generally used by people with serious, complex, chronic diseases to help absorb the cost of expensive specialty medications and/or medications without a medically equivalent generic. Accumulator adjustment programs subvert the benefit of co-pay assistance, thereby discriminating against people living with chronic conditions. One of our greatest concerns is the impact these programs may have on the ability of patients to adhere to their medications. Research has shown that over 70% of patients will not fill a prescription when their copayment reaches \$250 (the amount proposed for specialty medications in gold level standard plans), and even at half that amount (\$125), 55% of patients will opt against filling a new prescription. For patients with a serious condition like HIV, multiple sclerosis, cancer, epilepsy, hemophilia, or diabetes, delaying or forgoing treatment may result in severe deterioration of their condition, permanent disability or even death.

Our comments are all framed within the context of accumulator adjustment programs and their impact on patients. Below please find our comments on the specific questions within the FTC request for comments.

The impact of PBM rebates and fees on net drug prices to patients, employers, and other payers.

Patient cost-sharing is often tied to the list price, rather than the net price, of a drug. This can be particularly problematic when the patient is paying co-insurance for their drug, which can reach 40% in many plans. For specialty drugs like biologics that tend to be more expensive than other drugs, this could reach into the thousands of dollars per month per prescription, a cost that is out of reach for most Americans. It's this type of cost-sharing structure that makes co-pay assistance a vital lifeline for patients to be able to afford their out-of-pocket costs. There is research to suggest that

not passing rebates through to patients impedes the intentions of how insurance should work. Currently, PBMs argue that rebate dollars are used to keep premiums low for everyone, but this rationale imposes elevated costs on those with chronic or serious health conditions who rely on expensive medications and already pay the highest costs because of cost-sharing structures like co-insurance and lack of rebate pass through.

Specific examples include:

- Researchers from the Robert Wood Johnson Foundation found that the vast majority (81%) of silver level individual market plans in 2019 required enrollees to pay coinsurance for specialty drugs.¹
- According to the Kaiser Family Foundation, 85% of covered workers in American have a general annual deductible. The amount of that deductible has increased 13% over the last five years and 68% over the last 10 years.²

The impact of PBM rebates and fees on formulary design and patients' ability to access prescribed medications without endangering their health, creating unnecessary delay, or imposing administrative burdens for patients or prescribers.

The current system whereby manufacturers negotiate with PBMs for preferred formulary placement in exchange for higher rebates often leads to drugs with higher list prices gaining formulary preference specifically because the PBM can then extract higher rebates. This results in a perverse incentive for PBMs to choose a higher cost drug to be on the preferred formulary which increases rebate dollars for the PBM while allowing PBMs to simultaneously implement copay accumulator adjustment programs preventing patients from getting the assistance they need to pay for the high cost of that same drug. This creates a vicious cycle whereby a patient is required to take a higher cost drug due to its preferred formulary placement without allowing the patient to use copay assistance to help afford that medication. This intentional process negates PBMs claims that copay assistance simply incentivizes patients to take higher cost brand name drugs. Importantly, many specialty drugs have no generic or meaningfully lower cost alternative. Further, patients are typically in the dark about how much any given drug costs.

People with low incomes and people of color are more likely to be living with a chronic illness, and therefore, these policies target the most vulnerable patients, enabling insurance issuers to engage in what amounts to “backdoor” underwriting of insurance policies for people who require specialty or brand medications. As insurers have shifted more and more costs to enrollees – especially those who rely on specialty and brand medications – with higher deductibles and increasing coinsurance, many people living with chronic illness must rely on financial assistance to help cover the costs of their prescription drugs and remain adherent to their treatment. While most enrollees will never hit an out-of-pocket limit of \$9,100 (the proposed amount for 2023), people managing a chronic illness requiring higher cost preferred formulary drugs or specialty or nonpreferred brand medications may be forced to pay this amount every single year, often in the first few months of the year.

¹ K. Hempstead, Marketplace Pulse: Cost-Sharing for Drugs Rises Sharply at Higher Tiers (Robert Wood Johnson Foundation, March 1 2019), <https://www.rwjf.org/en/library/research/2019/03/cost-sharing-for-drugs-rises-sharply-at-higher-tiers.html> .

² Kaiser Family Foundation. (2022). Employer Health Benefits: 2021 Annual Survey. <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf> (pg. 9)

It is also important to point out that copay accumulators are in addition to and follow more traditional utilization management – where the patient would have already gone through prior authorization, step therapy, and other utilization management protocols before being subject to accumulators. The use of utilization management tools has increased overtime, with more than 94% of plans today reporting using UM to control costs and access.³ This means that the PBM or payer has already deemed the medication appropriate, but nonetheless employs the argument that patients are inappropriately choosing higher-cost drugs.

Specific examples include:

- An analysis of utilization management costs for the various stakeholders in the healthcare system reveals the intensive increase in applying restrictive access controls: the three largest PBMs moved from excluding 109 specialty drugs from their formularies in 2014 to 846 excluded drugs in 2020.⁴
- The Health Affairs study also calculated the economic impact that comes from implementing UM; while payers spend \$6 billion administering UM annually, providers spend nearly \$27 billion in time each year navigating the UM requirements and patients spend \$35 billion in drug cost-sharing. Patients are not simply selecting higher-cost drugs, but are navigating a complex system to get the medically appropriate treatments they desperately need.
- A study in the journal *Epilepsy and Behavior* found that 21% of adults with epilepsy have been unable to afford their medications at some time.⁵

Whether patients are being forced to substitute different prescription drugs to maximize PBM rebates and fees.

As discussed above, there are no generic and/or lower cost alternatives for many specialty drugs. While PBMs have the ability to negotiate in order to maximize their rebates and fees, many patients with serious, chronic health conditions lack a therapeutic equivalent, leaving them dependent on copay assistance to afford access to their medication. It is also important to point out that many specialty medications are complex and cannot be easily substituted. Patients develop specific immune responses to biologic medications and cannot simply switch to other medications indicated for their disease with different mechanisms of action. This makes it crucial that decisions about what medications to take occur between the provider and the patient, and that once the patient is prescribed a specific medication, they be allowed to remain on it without disruption.

Specific examples include:

- In the case of HIV, changing an antiviral regimen can cause a patient to become resistant to not only a single drug, but an entire class of antivirals. HIV specialists have stated that there are “many important considerations, including the person’s adherence to medications, drug resistance, drug-to-drug interactions, concomitant medical conditions and side effect

³ J. McSpadden, “Trends in Utilization Management of Prescription Drugs in Top Marketplace Plans,” (AARP Public Policy Institute, April 6, 2022). <https://www.aarp.org/ppi/info-2022/trends-utilization-management-top-drug-plans.html#:~:text=Today%2C%20more%20than%2094%20percent,to%20manage%20costs%20and%20access.>

⁴ S. Howell, P. Yin, J. Robinson, “Quantifying The Economic Burden of Drug Utilization Management on Payers, Manufacturers, Physicians, and Patients,” *Health Affairs Journal*, August, 2021.

⁵ Thurman, D.J., Kobau, R., Luo, Y., Helmers, S.L., & Zack, M.M. (2016). Health-care access among adults with epilepsy: The U.S. National Health Interview Survey, 2010 and 2013. *Epilepsy & Behavior*, 55, 184-88. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/>.

profiles [are] taken into account when choosing the best regimen.... it's medically crucial to have all options on the table when prescribing and to be able to start those drugs quickly, with no barriers to access."⁶ Clinical, not financial, reasons should drive health coverage policies.

- People living with epilepsy who have their medications switched, or who experience a delay in accessing their medication, are at a high risk for developing breakthrough seizures and related complications including death. Seizure-free people who switch drugs have an approximately 14% additional risk of seizure recurrence, compared to those remaining on the same drug.⁷

PBMs' use of other potentially unfair, deceptive, or anticompetitive practices, including audit provisions; pharmacy network design and exclusions; use of gag clauses, confidentiality clauses, and non-disparagement clauses; and other potentially unfair provisions.

In addition to the harm caused to patients by copay accumulator adjustment policies, these policies subvert the patient protections of the ACA by allowing insurers and PBMs to overcharge enrollees who use copay assistance. The ACA established annual out-of-pocket limits for covered health care services. When enrollees hit the out-of-pocket limit, insurance issuers must fully cover any further health care costs incurred. By not counting copay assistance cost-sharing amounts used to pay for covered services toward annual deductibles and out-of-pocket limits, insurers are able to keep the cost-sharing paid by enrollees and avoid assuming responsibility for costs above the out-of-pocket limit. This reduces the overall value of insurance for enrollees with chronic illness and exposes them to ongoing charges for their prescription drugs as well as any other health care they may need during the year.

We also have serious concerns with how accumulator programs are marketed to employers and communicated to patients. Copay accumulator programs are marketed to employers designing their benefits packages as a cost saving tool; however, evidence shows that patients experience negative health outcomes that could ultimately impact the individual's ability to remain in the workforce. A 2019 survey of a sample of large employers found that 34% were already using copay accumulator adjustment policies, and an additional 4% sought to add them in the next year – a significant increase over previous years.⁸ The three largest pharmacy benefit managers (PBMs) are now marketing copay accumulator adjustment policies to employers that are designing their insurance plans, which may be contributing to their increasing prevalence.⁹

Insurers are not required to disclose whether a particular plan contains a copay accumulator adjustment policy in plan materials that are made available to people prior to enrollment, such as in the standardized Summary of Benefits and Coverage that is required by the ACA. In

⁶ HIV Medical Providers Strongly Oppose Proposed Changes to Medicare Drug Plans "Protected Classes." POZ Magazine. January 2019. <https://www.poz.com/article/hiv-medical-providers-strongly-oppose-proposed-changes-medicare-drug-plans-protected-classes>

⁷ Finamore, J. M., Sperling, M. R., Zhan, T., Nei, M., Skidmore, C. T., & Mintzer, S. (2016). Seizure outcome after switching antiepileptic drugs: A matched, prospective study. *Epilepsia*, 57(8), 1294–1300. <https://doi.org/10.1111/epi.13435>

⁸ Kelsey Waddill, "Employers Focus on High-Cost Claims, Drug Spending into 2020," Xtelligent Healthcare Media, August 15, 2019, <https://healthpayerintelligence.com/news/employers-focus-on-high-cost-claims-drug-spending-into-2020>.

⁹ Aired Alliance, "An Update on Copay Accumulator Policies," 2019, <https://aimedalliance.org/an-update-on-copay-accumulator-policies/>.

a review of 234 ACA marketplace plans conducted by The AIDS Institute, the researchers found 15.4% of plans did not have any information about copay accumulator policies in plan documents, including 15 plans that did have copay accumulators as confirmed by customer service representatives.¹⁰

PBMs' policies and practices related to specialty drugs and pharmacies, including criteria for designating specialty drugs, reimbursements to specialty pharmacies, practices for encouraging the use of PBM-affiliated specialty pharmacies, and practices relating to dispensing high-cost specialty drugs over alternatives.

A rising trend of concern are programs like SaveOnSP which require patients to enroll into specific programs to receive their medications. While cost-sharing is often minimal or even zero, and therefore the patient is shielded from the need to use copay assistance, the payer or PBM is extracting the copay assistance directly from the manufacturer, furthering the perverse incentive structure of the rebate system. Contradicting payer and PBMs ongoing, parallel claim that copay assistance simply incentivizes patients to take higher cost brand name drugs, this practice requires patients to take action to facilitate and prompt the payment of copay assistance to payers and PBMs. Alarming, if the patient does not enroll in the program, they are told that their drug will not be considered an Essential Health Benefit and therefore the patient will not have an out-of-pocket maximum. This flies in the face of the intent of the Affordable Care Act, and has caused concern, fear, and financial hardship for many patients who have raised questions and examples of these programs to us.

ACCC members have received calls and letters from patients who have received notifications from their PBM requiring them to enroll in a SaveOnSP or other program or risk their drug being deemed non-essential. These notifications have unsurprisingly alarmed and concerned patients who receive these letters.

Potential conflicts of interest and anticompetitive effects arising from horizontal and vertical consolidation of PBMs with insurance companies, specialty pharmacies, and providers.

PBMs are restructuring the health care system by exerting greater control through rapid consolidation with insurance companies, specialty pharmacies, and providers. They pose a substantial threat to patient access of care by disrupting the health care market in order to extract higher profits. By promoting accumulator programs through these channels, we consider this consolidation as a conflict of interest.

Thank you for the opportunity to provide comments on the impact of PBM practices on patients. As organizations who represent millions of patients and providers impacted by serious and chronic diseases, this is a critically important topic. Please reach out to Anna Hyde, Vice President of Advocacy and Access at the Arthritis Foundation, at ahyde@arthritis.org or 202-843-0105 with any questions.

¹⁰ The AIDS Institute, "Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness: Copay Accumulator Adjustment Policies in 2022," (January 2022), https://aidsinstitute.net/documents/final_TAI_2022-Report-Update_020122.pdf

Sincerely,

AIDS Foundation Chicago
Alliance for Patient Access
Alpha-1 Foundation
American Academy of HIV Medicine
American Kidney Fund
Arthritis Foundation
Autoimmune Association
Cancer Support Community
Caring Ambassadors Program
Chronic Care Policy Alliance
Color of Crohn's and Chronic Illness
Crohn's & Colitis Foundation
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Epilepsy Foundation
Gaucher Community Alliance
HealthyWomen
Hemophilia Federation of America
HIV Dental Alliance
HIV Medicine Association
ICAN, International Cancer Advocacy Network
Immune Deficiency Foundation
Infusion Access Foundation (IAF)
International Foundation for AiArthritis
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Multiple Sclerosis Association of America
National Infusion Center Association (NICA)
National Hemophilia Foundation
National MS Society
National Psoriasis Foundation
Partnership to Fight Chronic Disease (PFCD)
Patient Access Network (PAN) Foundation
Prevention Access Campaign
Pulmonary Hypertension Association
SisterLove, Inc.
Susan G. Komen
The AIDS Institute
The Assistance Fund
Western Pennsylvania Bleeding Disorders Foundation