CENTER *for* HEALTH LAW
and POLICY INNOVATION
HARVARD LAW SCHOOL

May 25, 2022

Lina Khan
Chair, Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, DC 20580

Re: The Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Chair Khan,

The Center for Health Law and Policy Innovation (CHLPI) of Harvard Law School is grateful for the opportunity to comment on how business practices of Pharmacy Benefit Managers (PBMs) impact individuals living with HIV and other chronic conditions. CHLPI advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses.

CHLPI has extensive experience addressing discrimination in insurance benefit design, particularly designs that discriminate against people living with HIV who need reliable, affordable access to key treatments and services. About 1.2 million individuals live with HIV across the United States, with disproportionate representation from LGBT communities, communities of color, and people with low incomes.[1] When people living with HIV have regular access to effective antiretroviral therapy, many are able to suppress their viral loads to undetectable levels and have effectively no risk of sexually transmitting HIV.[2]

Despite the advent of effective treatments and clear individual health and public health benefits from reliable, affordable HIV treatment, only about half of people living with HIV in the United States receive adequate and sustained care.[3] High out-of-pocket costs is a key driver of this lack of sustained care.[4] PBM policies and practices related to specialty drugs often exclude component drugs used in

[1] 26 Ctrs. for Disease Control & Prevention, *HIV Surveillance Supplemental Report: Estimated HIV Incidence and Prevalence in the United States, 2015–2019* at 39 tbl.7 (2021); 32 Ctrs. for Disease Control & Prevention, *HIV Surveillance Report: Diagnosis of HIV Infection in the United States and Dependent Areas, 2019* at 12, 19 (2021); Paul Denning & Elizabeth DiNenno, *Communities in Crisis: Is There a Generalized HIV Epidemic in Impoverished Urban Areas of the United States?*, Ctrs. for Disease Control & Prevention (Dec. 11, 2019), https://bit.ly/3voYLyA.
[2] Dep't of Health & Hum. Servs. Panel on Antiretroviral Guidelines, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV* E-5 (2021).
[3] Ctr. for Medicaid & CHIP Servs., *Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries* at *5 (2016), 2016 WL 7177788.
[4] Dep't of Health & Hum. Servs. Panel on Antiretroviral Guidelines, *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV* at L-23 (2021) (collecting studies).

recommended treatment regimens or require individuals living with chronic conditions to pay thousands of dollars for their medications, as studies by CHLPI and other bodies indicate.[5]

The PBM's role at the nexus between pharmacies, insurers, and drug manufacturers, is also often shrouded in mystery, with little transparency as to how much drugs will cost consumers (specifically, when plans require coinsurance instead of copayments), what additional barriers people may face when accessing medications (such as mandatory mail order requirements, specialty pharmacy program enrollment, or mandatory enrollment in third party schemes that manipulate manufacturer assistance programs), and at times, why most or all drugs used to treat a certain condition are on the most expensive formulary tiers. The opaque relationships between these parties facilitate discriminatory formulary design and undermine regulatory efforts to enforce nondiscrimination protections. Specifically, PBMs can both act as common agents in designing discriminatory formularies for multiple plans and dampen effective competition by new entrants who are forced to rely on the services and formularies of the same PBMs that their much larger competitors have ongoing relationships with.

Finally, the steering of individuals toward affiliated mail-order pharmacies by PBMs harms individuals by eliminating their choice in the pharmacy market and forcing them to forego centralized pharmacist counselling. These vulnerable individuals are more likely to lack reliable access to medical care, and may rely on pharmacist counselling as one of their few ways to receive medical advice that takes all aspects of their health into consideration.

I. Formularies designed and maintained by insurers and PBMs drive individuals living with chronic conditions to shoulder significant cost-sharing burdens when accessing nationally-recommended guideline treatment regimens.

Many formularies designed by insurers and PBMs discriminate against individuals living with HIV by systemically imposing substantial cost sharing for nationally-recommended HIV medicine.

The Affordable Care Act prohibits health insurers from refusing to cover individuals with pre-existing conditions and from charging them higher premiums.[6] The law also requires most plans to provide prescription drug coverage as an essential health benefit.[7] Nondiscrimination standards also protect individuals living with disabilities, including HIV, from being excluded from participation in, denied benefits of, or subjected to discrimination in certain health programs and activities.[8] Nonetheless, formularies maintained by insurers and PBMs often discriminate against individuals living with HIV by systematically requiring substantial cost sharing for HIV medicine, if at all covered. This practice is known as adverse tiering and effectively dissuades individuals with disabilities (who have high lifetime medical costs) from joining particular insurance plans.[9] Multiple studies have shown that

[5] The empirical analysis outlined here focuses on systemically higher costs imposed on individuals living with HIV. But, the same discriminatory design trend and systemically higher out-of-pocket costs have been observed for a host of other diseases, such as Multiple Sclerosis (MS), Primary Immunodeficiency (PI), and Bipolar Disorder. See, e.g., Lisa Gillespie, *PhRMA, Advocates: Specialty Drug Costs for Patients Too High*, Kaiser Fam. Found. (June 12, 2014); https://bit.ly/3Op3dXh; Avalere, *An Analysis of Exchange Plan Benefits for Certain Medicines* 2–4 (2014), https://bit.ly/385lWq2.

[6] 42 U.S.C. §§ 300gg-3 to 4.

[7] 42 U.S.C. § 18022; 45 C.F.R. § 156.200(b)(3) (2021).

[8] Specifically, Section 1557 of the ACA, 42 U.S.C. § 18116, subjects plans to the disability antidiscrimination provisions of the Rehabilitation Act of 1973, 29 U.S.C. § 794. *See also Bragdon v. Abbott*, 524 U.S. 624, 631, 641–42 (1998).

[9] *See Doe v. CVS Pharmacy, Inc.*, 982 F.3d 1204, 1208–10 (9th Cir. 2020), *cert. granted*, 141 S. Ct. 2882 (2021), *cert. dismissed*, 142 S. Ct. 480 (mem) (2021).

these individuals pay significantly more out of their own pockets to purchase prescription drugs despite paying the same premiums as other individuals.[10]

An analysis of insurance plans offered in Illinois's Insurance Marketplace (Get Covered Illinois, using the Healthcare.gov platform) illustrates the extent of this discriminatory practice. Seven of the eleven plans sold on Illinois's Insurance Marketplace place more than half of combination drugs used in national treatment guidelines[11] in high-cost specialty tiers or outside of their formularies altogether. Consequently, individuals living with HIV who enroll in these plans are expected to pay $4,000–$14,000 (representing 6%–20% of Illinois's median household income[12]) out of their own pockets. In contrast, only four available plans do not engage in similar formulary design, requiring enrolled individuals with HIV to pay about $1,200-$4,000.

The impact of adverse tiering is not restricted to an individual's financial burden though. Many individuals who are unable to afford the cost of their life-saving medication rely on third party financial support, such as from the Ryan White HIV/AIDS Program.[13] In such a scenario, the federal money, used to provide for the "delivery of essential services to individuals and families with HIV"[14], covers additional expenses that result from discriminatory formulary design imposed by private insurance plans.[15]

II. The opaque relationship between PBMs, insurers, and manufacturers in a concentrated market facilitates the coordination of discriminatory formulary design and dampens competition by maverick new entrants.

PBMs sit at the nexus of opaque negotiations between insurers on one side and drug manufacturers on the other.[16] Terms of these negotiations are treated as highly confidential trade secrets such that, because PBMs act as intermediaries, insurers and drug manufacturers sometimes have little visibility into the final prices and rebates paid for each prescription.[17] Consumers additionally have even less visibility into final costs, making it near impossible to determine how much a consumer with known prescription drug needs will have to pay if their medications are subject to coinsurance (where the consumer pays a percentage of the unknown negotiated drug cost) instead of copayments (where the consumer pays a pre-determined flat fee).

---

[10] *See, e.g.*, Douglas B. Jacobs & Benjamin D. Sommers, *Using Drugs to Discriminate—Adverse Selection in the Insurance Marketplace*, 372 New Eng. J. Med. 399, 400 (2015); Sara B. McMenamin et al., *Addressing Discriminatory Benefit Design for People Living With HIV: A California Case Study*, 29 AIDS Care 1594, 1595 (2017).

[11] Dep't of Health & Hum. Servs. Panel on Antiretroviral Guidelines, *supra* note 4, at G-4 tbl.6.

[12] The median household income stood at about $66,000 in 2019. *QuickFacts: Illinois*, U.S. Census Bureau (2019), https://www.census.gov/quickfacts/fact/table/IL/BZA210219.

[13] Judith A. Johnson & Elayne J. Heisler, Cong. Rsch. Serv., Report No. R44282, *The Ryan White HIV/AIDS Program: Overview and Impact of the Affordable Care Act* 17 (2015), https://bit.ly/3jgezPq.

[14] 42 U.S.C. § 300ff.

[15] *See* Johnson & Heisler, *supra* note 13, at 17 (citing Jeffrey S. Crowley & Connie Garner, *Aligning The Ryan White HIV/AIDS Program With Insurance Coverage* (O'Neill Inst. for Nat'l & Glob. Health L. at Georgetown L., Issue Brief No. 1, June 2015), https://bit.ly/3pqsiat).

[16] FTC & Dep't of Just., *Improving Heath Care: A Dose of Competition* ch. 7, § 5 (2004); Panos Kouvelis et al., *Drug Pricing for Competing Pharmaceutical Manufacturers Distributing Through a Common PBM*, 27 Prod. & Operations Mgmt. 1399, 1399–1400 (2018).

[17] *Run it First, LLC v. CVS Pharmacy, Inc.*, No. 21-22604-Civ-Scola, 2022 WL 484862, at *1-2 (S.D. Fla. Feb. 16, 2022); Elizabeth Seeley & Aaron S. Kesselheim, Commonwealth Found., *Pharmacy Benefit Managers, Practices, Controversies and What Lies Ahead* 2–3 (2019), https://bit.ly/3uXC0Dv.

The influence of these opaque negotiations on formulary design can be problematic for people living with ongoing pharmaceutical needs, particularly when formularies are designed in a manner that places necessary medications out of reach. Over time, for example, insurers may find that people living with chronic conditions who require prescription drugs will enroll in plans that do not employ discriminatory formulary designs. This will encourage insurance plans to "race to the bottom" so people requiring these medications are discouraged from enrolling in their plans.[18] The regulatory counterweight to this pressure has been to stymie it at its onset by regularly reviewing formularies and flagging those that are outliers from peer plans.[19] However, a coordinated change in formularies with PBMs acting as common agents renders this screening process ineffective when most or all plans employ the same design issues.

This power structure also facilitates the spread of discriminatory formularies by dampening competition by maverick new entrants. According to IBISWorld, the three largest PBMs (CVS Health Corporation, Cigna Corp, and UnitedHealth Group Incorporated) control about 80% of the PBM market.[20] Potential and actual entry into state health insurance markets is a crucial competitive check on incumbent, and often larger, insurance firms.[21] New entrants often provide some of the most affordable insurance options in the market; however, the dominant position of PBMs often means that new entrants have to go through PBMs to access pharmacy networks and process drug prescriptions.[22] This *de facto* obligation of new entrants to deal with PBMs, in turn, dampens the entrants' competitive thrust. Namely, new entrants typically have to outsource most of their formulary design and management activities to PBMs as a part of these deals.[23] Consequently, they lose the ability to use their formularies as an effective competitive tool to draw a wedge in the market.

III. The steering of individuals towards mail-order specialty pharmacies affiliated with PBMs can have a discriminatory impact on individuals living with chronic conditions.

Many PBMs actively steer individuals living with chronic conditions towards in-house mail-order pharmacies instead of the independent third-party pharmacies that members have pre-existing relationships with for their medical care.[24] For example, a person may be able to get their non-HIV

[18] *See* Douglas B. Jacobs & Benjamin D. Sommer, *Using Drugs to Discriminate — Adverse Selection in the Insurance Market Place*, 372 New. Eng. J. Med. 399, 401 (2015); Douglas Jacobs & Robert Restuccia, *Ensuring a Discrimination-Free Health Insurance System*, Health Affs. (June 11, 2015), https://bit.ly/3JVnC2D.

[19] Ctr. for Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Servs., *2022 Final Letter to Issuers in the Federally Facilitated Marketplaces* 11 (2021), https://go.cms.gov/3l1QVYk; Ctr. for Consumer Info. & Ins. Oversight, Ctrs. for Medicare & Medicaid Servs., *Addendum to 2018 Letter to Issuers in the Federally-Facilitated Marketplaces* 46–4 (2017), https://go.cms.gov/3a0yz3v.

[20] Arnez Rodriguez, IBISWorld, *Industry Report OD4620*, *Pharmacy Benefit Management* 8 (2021).

[21] *See* Daniel McDermott & Cynthia Fox, *Insurer Participation on the ACA Marketplaces, 2014–2021*, Kaiser Fam. Found. (Nov. 23, 2020), https://www.kff.org/private-insurance/issue-brief/insurer-participation-on-the-aca-marketplaces-2014-2021/.

[22] *See* FTC & Dep't of Just., *supra* note 16 (noting that insurers that want to expand across state lines has to rely on a handful of large PBMs that have the necessary national reach); *see also* Health Affs., *Health Policy Brief Series 12*, *Pharmacy Benefit Managers* 2 (2017), https://bit.ly/3JZkVgu (discussing factors that have turned PBMs into necessary transaction partners for insurers).

[23] *See* Chris Kukka & Jane Horvath, *Pharmacy Benefit Manager Model Legislation: Questions and Answers*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Aug. 9, 2018), https://bit.ly/3EBJz64.

[24] In addition to steering individuals living with chronic conditions to enroll in required specialty pharmacies, some PBMs also work with plans to require some individuals with chronic conditions to enroll in third party programs that manipulate manufacturer or other assistance programs in order to pocket the assistance money. Copay maximizer programs like SaveonSP (owned by Cigna and affiliated with ExpressScripts) and PrudentRx (owned by CVS and affiliated with Accredo) attempt to circumvent ACA protections by redesignating certain specialty drugs as "non-essential health benefits," forcing patients to enroll in

medications from their neighborhood brick-and-mortar pharmacy, but would be required to obtain their HIV medications from an in-house mail-order specialty pharmacy instead. While this active steering of individuals often leads to revenue growth, it eliminates individual choice in the pharmacy market and forces individuals taking certain medications to obtain those drugs via mail delivery from a PBM-affiliated pharmacy. [25]

The active steering of individuals living with chronic conditions toward an in-house mail-order pharmacy also forces individuals to forego centralized pharmacist counseling.[26] Pharmacists are often the only ones that can "(i) detect potentially life-threatening adverse drug interactions and dangerous side effects, some of which may only be detected visually; [and] (ii) immediately provide new drug regimens as [individuals'] disease progresses . . . ."[27] Furthermore, splitting the dispensing of specialty and non-specialty medications between multiple pharmacies makes it difficult for any single pharmacist to track a patient's medical history and to identify potentially life-threatening drug interactions.[28] Additionally, drug delivery through mail often has a disproportional impact on individuals living with certain chronic conditions, such as HIV, because such deliveries can compromise their privacy and subject them to stigmatization and discrimination due to their diagnosis.[29] Moreover, delivery of drugs through mail often creates uncertainty for individuals and their medical team who may be concerned about the medicine having been compromised due to exposure to elements and extreme temperatures.[30]

The increasing exclusive reliance on PBM-affiliated mail-order pharmacies for specialty medications also puts significant pressure on local, independent pharmacies, with a disproportional impact on pharmacies serving rural and remote communities.[31] With affiliated mail-order pharmacies receiving preferential reimbursement rates, many local and independent pharmacies have gone out of business. This, in turn, has a disproportional impact on individuals living with chronic conditions in rural and remote communities who often only have one or two independent pharmacies serving their area and who may not want to rely on mail-order delivery for necessary drugs due to unreliable

---

manufacturer copay assistance programs in violation of the terms of those programs, or forgo their necessary, lifesaving medication. *See, e.g.*, David Cook, IPBC and SaveonSP Training-20210216 1901-1, VIMEO (Feb 17, 2021), https://vimeo.com/513414094 (describing SaveonSP's scheme to get the "most lucrative savings" by reclassifying specialty drugs as "non-essential," allowing SaveonSP to "operate outside of those [Affordable Care Act] rules"); PrudentRx Copay Program for Specialty Medications, https://personnel.ky.gov/KEHP/PrudentRx%20Overview.pdf (accessed May 25, 2022) ("certain specialty drugs do not qualify as 'essential health benefits'"); Peter Loftus, *J&J Sues Drug Benefit Middleman Over Use of Drug-Cost Assistance Program*, Wall Street Journal (May 4, 2022), https://www.wsj.com/articles/j-j-sues-drug-benefit-middleman-over-use-of-drug-cost-assistance-program-11651698029 (describing recent lawsuit against SaveonSP).

[25] Rodriguez, *supra* note 20; FTC, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* at i (2005).

[26] N.Y. State Senate Comm. on Investigations & Gov't Operations, *Final Investigative Report: Pharmacy Benefit Managers in New York* 63–64 (2019).

[27] *CVS Pharmacy, Inc.*, 982 F.3d at 1208 (internal quotation marks omitted).

[28] *CVS Pharmacy, Inc.*, 982 F.3d at 1208; Brief for the Center for Health Law and Policy Innovation of Harvard Law School, et al. as Amicus Curiae Supporting Respondents at 23-26, CVS Pharmacy, Inc. v. John Doe, No. 20-1374 (U.S. Oct. 29, 2021) [hereinafter CHLPI Amicus Brief]

[29] CHLPI Amicus Brief at 11-12.

[30] CHLPI Amicus Brief at 13-22; N.Y. State Senate Comm. on Investigations & Gov't Operations, *Final Investigative Report: Pharmacy Benefit Managers in New York* 63–64 (2019).

[31] See, e.g., Markian Hawryluk, *How Rural Communities are Losing Their Pharmacies*, Kaiser Health News (Nov. 15, 2021), https://khn.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/.

parcel delivery.[32] This threatens the regular supply of medicine to individuals, and in the case of individuals living with HIV, even brief interruptions can lead to treatment failure and more aggressive and expensive follow-on care.[33]

* * *

In conclusion, the role played by PBMs in an opaque and highly concentrated market has a direct impact on individuals living with chronic conditions, as the consequences of PBM practices can put life-saving medications out of reach. For people who rely on regular access to health care, regulation of this market and enforcement of nondiscrimination standards are vital.

We thank the Federal Trade Commission for the opportunity to submit these comments and share how the business practices of PBMs impact consumers living with HIV and other chronic conditions. Please feel free to contact us directly with any questions.

Sincerely,

Maryanne Tomazic
Clinical Instructor
Center for Health Law and Policy Innovation
mtomazic@law.harvard.edu

[32] U.S. Postal Serv., *Report No. RISC-WP-20-008*, *RISC Report: Package Delivery in Rural and Dense Urban Areas* 11–13 (2020); CHLPI Amicus Brief at 14-15, 20.
[33] Dep't of Health & Hum. Servs. Panel on Antiretroviral Guidelines, *supra* note 4, at I-1.