May 25, 2022

Commissioner Chair Lina Khan
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Request for Information on Pharmacy Benefit Managers' Practices

Dear Commissioner Khan:

Aimed Alliance is a 501(c)(3) not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the opportunity to provide information to the Federal Trade Commission (FTC) on Pharmacy Benefit Managers' (PBMs) Business Practices (Docket ID FTC-2022-0015). In particular, we would like to raise awareness about how PBMs are:

(1) partnering with certain companies to unfairly force patients who are prescribed specialty medications to enroll in non-essential health benefit (non-EHB) and alternative funding schemes that seek to maximize financial assistance dollars available to these patients to the benefit of the plan; and
(2) increasing overall health care costs.

I. Background

PBMs are businesses that plan sponsors contract with to administer their prescription drug benefits. PBMs act as intermediaries between plans, drug manufacturers, and pharmacies to negotiate discounts and rebates with drug manufacturers in exchange for the health plan placing a drug on a plan formulary.[1] However, due to the lack of oversight on PBM practices, PBMs can implement anticompetitive practices that increase drug prices; impose rebates that are not passed to consumers or insurers; and impair patient access to treatment through mid-year formulary exclusions.[2] As explained below, PBMs also have recently begun partnering with other companies (e.g., SaveOnSP, PrudentRx, PayorMatrix, PaydHealth, etc.) to force consumers into non-EHB and alternative funding schemes to receive their specialty medications.

A. Non-EHB Schemes

When patients cannot afford their prescriptions medications, eligible patients may rely on financial assistance from non-profit organizations, drug manufacturers, and other sources

[1] Aimed Alliance, *Drivers of Health Costs in the U.S. Part II: Understanding the Pharmacy Benefit Manager's Role*, https://aimedalliance.org/wp-content/uploads/2017/11/Drivers-of-Health-Costs-in-the-US-Part-II.pdf .
[2] *Id.*

(collectively referred to as patient assistance programs or PAPs) to help meet their cost-sharing requirements for their medications. This is especially true of vulnerable patients with serious, complex, or chronic conditions who are prescribed specialty drugs for which there are no generic alternatives. Typically, PAP assistance should be applied to the patient's deductible and annual out-of-pocket limits. However, health plans and PBMs have recently implemented what are known as "copay accumulator programs."[3] Under copay accumulator programs, the health plan or PBM will accept the financial assistance from the PAP; yet, those dollars are not counted toward the patient's deductible or annual out-of-pocket limit.[4] In other words, copay accumulator programs are used to capitalize on PAP assistance for the benefit of the plan but to the detriment of patients.

Recently, health plans and PBMs have expanded this practice to further exploit PAP assistance by contracting with third-party companies to manage their specialty medication benefits through non-EHB[5] and alternative funding schemes.[6] PBMs actively market these partnerships to health plans as a solution for lowering plan costs.[7] However, these schemes are unfairly structured to exploit PAPs and force patients who are prescribed specialty medications to enroll in these schemes.

Under non-EHB schemes, patients who are prescribed specialty medications are told that they must enroll in the third-party company's specialty program to receive their drugs for $0 or at a low-cost.[8] These programs fulfill this promise by determining the maximum amount of PAP assistance available for a specialty medication for the entire year and then dividing that amount by 12 to determine the amount of monthly assistance available.[9] Once the monthly amount of assistance available is determined, these schemes set the monthly copay to at least the monthly amount of PAP available.[10]

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[3] Spondylitis Association of America, *Copay Accumulators Programs: What They Are And How They Might Impact Your Out-Of-Pocket Costs,* https://spondylitis.org/spondylitis-plus/copay-accumulator-programs-what-they-are-and-how-they-might-impact-your-out-of-pocket-costs/ .

[4] SaveonSP, *Employers FAQ,* https://saveonsp.com/employers/; PrudentRx, *The PrudentRx Copay Program Frequently Asked Questions,* at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf.

[5] Examples include SaveonSP, PrudentRx, and PillarRx.

[6] Examples include PayorMatrix, SharkRx.

[7] ExpressScripts, *SaveonSP*, https://www.express-scripts.com/corporate/solutions/lowering-costs#saveonsp; *See also*, Human Resources County of San Luis Obispo, *Save on Specialty Medications with Express Scripts SaveOnSP*, https://www.slocounty.ca.gov/Departments/Human-Resources/Department-News/Save-on-Specialty-Medications-with-Express-Scripts.aspx; While these outside companies are marketed as unrelated partners to PBMs, these schemes have been pitched to plans by a PBM and not by representatives of the third-party companies *See e.g.* IPBC and SaveonSP Training – 20210216, https://vimeo.com/513414094 (SaveonSP is pitched to health plans by an ExpressScripts representative); *see also* New Mexico Retiree Health Care Authority Annual Meeting, *Annual Meeting of the Board of Directors*, https://www.nmrhca.org/wp-content/uploads/2021/07/2021-7-15-Board-Book.pdf.

[8] IPBC and SaveonSP Training – 20210216, https://vimeo.com/513414094.

[9] *Id.*

[10] *Id.*

The third-party companies justify this practice by classifying specialty drugs as non-EHBs.[11] An EHB is an important designation under the Patient Protection and Affordable Care Act (ACA). Under the ACA, health plans must cover a set of ten types of EHBs, one of which is prescription drugs.[12] For prescription drugs, all cost-sharing by or on behalf of the patient should be counted towards meeting the patient's deductible and annual out-of-pocket limit. However, by deeming specialty drugs as non-EHBs—even for individuals with serious, complex, or chronic conditions who truly need these medically necessary treatments—these schemes allow the third-party program to capitalize on the maximum amount of PAP assistance available without applying the assistance toward the patient's deductible or annual out-of-pocket limits.[13]

Additionally, these non-EHB schemes are coercively structured to ensure that patients will enroll in the third-party specialty medication program. Specifically, these programs coerce patients into enrolling by stating that if patients do not wish to enroll in these programs they will be responsible for a coinsurance payment—which can run between 30 to 70 percent—and this payment will not count towards their deductible or annual out-of-pocket limit.[14] As a result, patients are left with no choice other than to enroll in these third-party programs to avoid unmanageable coinsurance payments.

B. Alternative Funding Schemes

Health plans and PBMs have taken non-EHB schemes one step further by implementing what are known as alternative funding programs. These schemes operate almost identically to non-EHB schemes, in that health plans and PBMs partner with third-party companies to manage specialty medication benefits, impose the same coercive enrollment structure, and exclude the PAP assistance from counting towards the patient's deductible and annual out-of-pocket limit.[15] However, alternative funding schemes are distinguishable from non-EHB programs because alternative funding schemes target a broader range of PAP assistance— while non-EHB schemes primarily target manufacturer PAP programs, alternative funding schemes typically also target assistance from foundations, non-profits, or other charitable sources.[16]

In addition, PAPs from charities and foundations often have income-eligibility requirements that many patients do not qualify for, but the third-party company still applies for it on the patients' behalf even if the patient is ultimately denied. Under alternative funding schemes, some program materials state "if a member does not qualify for a program the medication will go back

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[11] *Id.*

[12] *See generally*, CMS, *Information on Essential Health Benefits (EHB) Benchmark Plans,* https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.

[13] *Id.*; SaveonSP, https://saveonsp.com/.

[14] *Id.* ; PrudentRx, PrudentRx Copay Program Frequently Asked Question, https://www.pcsb.org/cms/lib/FL01903687/Centricity/Domain/200/Member%20FAQ-%20The%20PrudentRx%20Copay%20Program.pdf.

[15] CareFactor, *PaydHealth Program,* https://www.wchcs.org/Downloads/Paydhealth%20general%20letter%20for%20EMPLOYEES.pdf .

[16] *Id.*

through the [PBM] and be processed under the plan prescription benefit."[17] This back and forth from the PAP back to the plan can be confusing for patients and cause delays between when a patient is denied PAP assistance and when the necessary medication is processed back through the plan.[18] For patients with complex and chronic conditions, delays in accessing their medically necessary treatments can result in patients continuing to experience symptoms without relief, further deterioration of their health, and other long-term health consequences.

II. Non-EHB and Alternative Funding Schemes Are Unfair Practices

Under Section 5(a) of the Federal Trade Commission Act (FTC Act), the FTC has authority to prevent corporations from using "unfair or deceptive acts or practices in or affecting commerce."[19] For the FTC to have jurisdiction over the conduct at issue, the business practice must be either deceptive or unfair; it is not required to be both deceptive and unfair.[20] The FTC has authority to regulate unfair practices when the Commission has "reason to believe" a violation has occurred.[21] A practice is unfair where the practice (1) causes or is likely to cause substantial injury to consumers; (2) cannot be reasonably avoided by consumers; and (3) is not outweighed by countervailing benefits to consumers or competition.[22]

Based on our analysis, we believe that non-EHB and alternative funding schemes are unfair as defined by the FTC Act. Therefore, we urge the FTC to investigate these practices and take appropriate action.

A. Non-EHB and alternative funding schemes cause or are likely to cause substantial injury to consumers.

A substantial injury occurs when a consumer experiences a genuine harm.[23] The FTC applies an objective test to determine if a genuine harm has occurred.[24] Emotional distress is usually insufficient, however, a financial injury will satisfy the genuine harm requirement.[25]

Non-EHB and alternative funding schemes cause consumers to experience financial losses. When a consumer is forced to enroll in a special third-party program under either of these schemes, these programs collect PAP assistance on behalf of the consumer, but do not count this

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[17] *Id.*
[18] *Id.*
[19] FTC, *A Brief Overview of the Federal Trade Commission Investigative, Law Enforcement, and Rulemaking Authority*, https://www.ftc.gov/about-ftc/mission/enforcement-authority .
[20] *Id.*
[21] *Id.*
[22] FTC, *Federal Trade Commission Act: Section 5: Unfair or Deceptive Acts or Practices*, at p. 8, https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf .
[23] *Id.*
[24] FTC, *The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection,* https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection .
[25] *Id.*

assistance towards meeting the consumer's deductible or annual out-of-pocket limit.[26] As a result of the PAP assistance not being counted towards the consumer's deductible or annual out-of-pocket limit, the individual is required to pay thousands of additional dollars before they reach their deductible and annual out-of-pocket limit. In other words, because PAP assistance is accepted for the plan's benefit and not counted towards the consumers deducible or annual out-of-pocket limit, consumers lose the full financial benefit of the PAP assistance. As such, these schemes cause consumers to experience genuine financial harm.

B. Consumers cannot reasonably avoid enrolling in these programs.

The FTC has found that a practice is not unfair if a consumer can reasonably avoid the injury.[27] However, a practice may be considered unfair if the consumer is coerced into purchasing unwanted products or services.[28]

As explained in Section I above, non-EHB and alternative funding schemes are structured to coerce consumers to enroll in the third-party specialty medication benefits programs. These schemes present consumers with two bad options, either of which leads to financial injury. If consumers enroll in these programs, then their PAP assistance will be collected for the benefit of the plan and not count towards their deductible or annual out-of-pocket limit. If they do not enroll, then they are required to pay between a 30 to 70 percent coinsurance and, on top of that, the coinsurance *still will not* count towards their deductible or annual out-of-pocket limit.[29] As a result, most consumers are forced to choose the lesser of two evils—enrollment. In short, there is no reasonably way for consumers who are prescribed a specialty medication that is managed by a third-party program to avoid an injury from these programs.

C. Allowing non-EHB programs and alternative funding schemes to collect PAP assistance and not count this assistance towards deductibles and annual out-of-pocket limits does not benefit consumers or competition.

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[26] SaveonSP, *Employers FAQ*, https://saveonsp.com/employers/; PrudentRx, *The PrudentRx Copay Program Frequently Asked Questions*, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf; CareFactor, *PaydHealth Program*, https://www.wchcs.org/Downloads/Paydhealth%20general%20letter%20for%20EMPLOYEES.pdf.

[27] FTC, *Federal Trade Commission Act: Section 5: Unfair or Deceptive Acts or Practices*, at p. 8, https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf .

[28] *Id.*

[29] SaveonSP, *Employers FAQ*, https://saveonsp.com/employers/; PrudentRx, *The PrudentRx Copay Program Frequently Asked Questions*, at p. 1, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf; CareFactor, *PaydHealth Program*, https://www.wchcs.org/Downloads/Paydhealth%20general%20letter%20for%20EMPLOYEES.pdf; PaydHealth, *Select Drugs and Product Program Questions & Answers*, https://mennonitevillage.org/wp-content/uploads/2021/03/Select-Drugs-and-Products-Program_HR-FAQ-2020-03.pdf.

Lastly, for a practice to be unfair, its overall net effect on consumers must be negative, and any harm incurred by the consumer cannot be outweighed by an alternative benefit to consumers or competition.[30]

Non-EHB and alternative funding schemes do not have an underlying benefit to consumers or competition that would outweigh the net harm experienced by consumers forced to enroll in these programs. While plans, PBMs, and the partnering companies operating these schemes would likely argue that consumers receive a net benefit because they receive their medications for a low-cost or for $0, this argument ignores the fact that in the larger picture of the plan year, these programs cost patients thousands of additional dollars per year as they work to meet their deductible and annual out-of-pocket limit. For example, the Aids Institute estimated that when an individual patient is subject to a copay accumulator program, the individual can pay over $7,000 a year in *additional* health care costs.[31] As a result, the short term benefit of paying less at the pharmacy counter for a specialty drug does not outweigh the additional financial pressures that consumers experience as a result of not having assistance counted toward their deductibles and annual out-of-pocket limits. As such, the long-term financial harm outweighs any short-term benefit under these programs, and the overall net impact of these programs is negative for consumers.

In summary, we feel strongly that non-EHB and alternative funding schemes satisfy the definition of an unfair practice under the FTC Act. Therefore, Aimed Alliance encourages the FTC to further investigate these programs and take action as it sees fit.

III. PBMs Contribute to the Rising Cost of Health Care

As mentioned above, PBMs play a unique role in negotiating prices between health plans and drug manufacturers.[32] However, due to the lack of oversight of PBMs they can exploit this position and, as a result, increase overall health care costs. For example, under non-EHB and alternative funding schemes, PBMs are inflating the cost of specialty medications because they are basing the patient's cost-sharing requirements on the maximum amount of PAP assistance available, not on the actual negotiated price of the specialty medication.[33]

Moreover, as the middleman between health plans and drug manufacturers, PBMs often negotiate rebates with drug manufacturers in exchange for placing their medication on the PBMs' formularies.[34] However, due to the lack of transparency surrounding these rebate

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[30] FTC, *Federal Trade Commission Act: Section 5: Unfair or Deceptive Acts or Practices*, at p. 8, https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf .

[31] The Aids Institute, *Discriminatory Copay Policies Undermine Coverage for People with Chronic Illnesses Copay Accumulator Adjustment Policies in 2022*, at p. 7, https://aidsinstitute.net/documents/final_TAI_2022-Report-Update_020122.pdf .

[32] Aimed Alliance, *Drivers of Health Costs in the U.S. Part II: Understanding the Pharmacy Benefit Manager's Role*, https://aimedalliance.org/wp-content/uploads/2017/11/Drivers-of-Health-Costs-in-the-US-Part-II.pdf .

[33] IPBC and SaveonSP Training – 20210216, https://vimeo.com/513414094.

[34] *Id.* at p. 6.

practices, these rebates are not often passed on to health plans. As a result, the rebates are also not passed on to consumers to help lower their costs.[35] While some states, like Colorado,[36] have recently passed legislation to require PBMs to pass 100 percent of these rebates to the health plan or individual, this type of legislation has not been widely passed by the states. Therefore, the vast majority of consumers in the U.S. currently do not have similar state laws or regulations with these protections.[37]

Lastly, a lack of safeguards on PBM practices can also cause patients to experience mid-year interruptions in access to their medically necessary treatments. PBMs often engage in a practice known as non-medical switching in which the PBM removes a medication from the formulary, places a medication on a higher tier, or imposes another financial barrier, that forces a patient to change medications.[38] As a result of this PBM practice, patients are forced to switch medications for financial rather than medical reasons. These switches are particularly unfair to patients as these changes can occur at any time during the plan year, thereby depriving the patient of their expected coverage at plan enrollment.[39]

Thus, Aimed Alliance encourages the FTC to investigate these practices and take appropriate action to (1) ensure consumers are protected from schemes that artificially inflate the cost of specialty medications; (2) ensure consumers benefit from PBM negotiated rebates; and (3) prohibit PBMs from engaging in practices like non-medical switching that can interfere with a stable patient's health.

IV. Conclusion

In conclusion, we applaud the FTC for its leadership on requesting information on how PBM practices impact consumers and the health care system. We encourage the FTC to further investigate PBM practices that are unfair or deceptive; that increase the cost of health care; and those that impair patient access to necessary treatments; and take enforcement action as the FTC deems appropriate.

Thank you,

Ashira Vantrees
Staff Attorney

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[35] *Id.*

[36] Colorado General Assembly, *Coverage Requirements for Health-care Productions,* https://leg.colorado.gov/bills/hb22-1370.

[37] *Id.*

[38] Aimed Alliance, *Nonmedical Switching,* https://aimedalliance.org/nonmedical-switching/ .

[39] AfPA, *Non-Medical Switching A Position Statement from the Alliance for Patient Access,* https://admin.allianceforpatientaccess.org/wp-content/uploads/2020/02/AfPA-Position-Statement-Non-Medical_Switching_July-2019.pdf .