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May 20, 2022

The Honorable Lina M. Khan
Chair
Federal Trade Commission (FTC)
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

RE: Role of PBMs on Patient Access and Affordability of Prescription Drugs

Dear Chair Khan:

The Alliance for Aging Research (“Alliance”) supports and appreciates the Federal Trade Commission’s (FTC’s) study of pharmacy benefit managers’ (PBM) business practices and their impact on the healthcare system at large. The Alliance is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health.

The Alliance is concerned that many common PBM business practices prevent beneficiaries from deriving full benefit from their Medicare Part D prescription coverage, restrict equitable access to necessary pharmaceutical care, and force those who are sickest to pay the highest out-of-pocket costs. At the same time, thoughtful reform of the role of PBMs can improve competition, reduce costs, and provide optimal value for taxpayers and beneficiaries. We thank the FTC for the opportunity to comment on these important issues.

Overview of PBM practices

Rebates

PBMs manage prescription drug benefits, most commonly for insurers and employers. In this role, PBMs establish standard drug formularies and help negotiate discounts from pharmaceutical companies, passing along some of the savings to health insurance plans and beneficiaries. However, this rarely works in practice for patients, who see little of the financial benefit from PBMs. For example, a standard practice in negotiating discounts is to ask for larger discounts off a drug’s list

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price in exchange for preferential placement on a PBM's formulary. There is considerable market pressure to participate and provide substantial discounts, as three major PBMs serve approximately 80 percent of the market.¹ If a drug is left off even one of the three's formularies, the manufacturer loses access to a large share of the market, incentivizing them to offer higher rebates to avoid exclusion from formularies. However, this introduces incentives for formulary placement that have little to do with clinical effectiveness.

This need for manufacturers to increase a drug's list price, and then increase its rebate to be competitive, leads to a significant gap in a drug's list price vs. net price. This gap has major consequences for consumers, whose out-of-pocket costs are based off list prices. According to a 2020 report from the USC Schaeffer Center, on average a \$1 increase in rebates is associated with a \$1.17 increase in list price.² Currently, the drug rebate savings flow entirely to PBMs and partnering insurers (and sometimes employers), while uninsured patients are forced to pay the increased list prices and insured patients are charged higher coinsurance/deductibles. Higher list prices also contribute heavily to consumer healthcare spending overall. According to a Kaiser Family Foundation report, half of all Part D covered drugs had list price increases greater than inflation between July 2019 and July 2020.³ These price increases fall directly on beneficiaries when they are required to pay coinsurance, which is common for many brand-name Part D drugs.

There is growing evidence that the growth rate of drug rebates is far outstripping the growth in net price of drugs, raising important questions about how PBM practices contribute to rising list prices for drugs. In 2019, the Government Accountability Office (GAO) conducted a study on the use of PBMs and efforts to manage drug expenditures and utilization in Medicare Part D.⁴ The study found that gross Part D expenditures increased by 20 percent between 2014 and 2016, from \$120.7 billion in 2014 to \$145.1 billion in 2016. Rebates and other price concessions increased 66 percent during the same period, while net Part D expenditures only increased by 13 percent.⁵ As a result, most of the growth in prescription drug costs came from PBM rebates and price concessions, rather than from increases in net expenditures, thereby creating an undue burden on patients who rely on Medicare Part D for access to pharmaceutical care.

¹ Fein, Adam J. "The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation." Drug Channels. 6 April 2021. <https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html>

² Sood, Neeraj; Ribero, Rocio; Ryan, Martha; and Van Nuys, Karen. "The Association Between Drug Rebates and List Prices." USC Schaeffer White Paper Series. Feb 2020. <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/>

³ Cubanski, Juliette and Neuman, Tricia. "Prices increased Faster Than Inflation for Half of all Drugs covered by Medicare in 2020." Kaiser Family Foundation. 25 Feb 2022. <https://www.kff.org/medicare/issue-brief/prices-increased-faster-than-inflation-for-half-of-all-drugs-covered-by-medicare-in-2020/>

⁴ Government Accountability Office. "Medicare Part D: Use of Pharmacy Benefit Managers and efforts to Manage Drug Expenditures and Utilization." Aug 2019. <https://www.gao.gov/products/gao-19-498>

⁵ Ibid.

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This can mean substantial changes in a patient's level of care, as evidence shows patients are more likely to abandon treatment as costs increase. According to a 2019 report from the IQVIA Institute, more than 40 percent of patients abandon their prescriptions at the pharmacy counter when out-of-pocket costs reach between \$75-\$125.⁶ Analysis of Medicare data also found that OOP cost growth of just \$10.40 per prescription leads to a 23 percent drop in total drug consumption and a 33 percent increase in monthly mortality.⁷ Older adults on fixed incomes are often forced to make difficult decisions between purchasing necessities like rent and groceries or their medications. This is particularly true for disadvantaged, minority patients and those living in rural areas that often have limited access to providers and pharmacies. For these reasons, the Alliance supports PBM rebate reform, including policies that would base patient coinsurance/copayments on net price rather than list price. A September 2021 Morning Consult survey commissioned by the Alliance showed that 86 percent of individuals aged 60 and older supported these reforms.⁸

Drug tiering and spread pricing

Within a PBM formulary, drugs are divided into tiers or benefit categories according to cost and required level of cost-sharing. There can be up to seven formulary tiers, with the lowest tiers representing drugs that are preferred/generic and the uppermost tiers containing higher-cost, specialty drugs used to treat complex, chronic conditions like cancer, rheumatoid arthritis, and multiple sclerosis.⁹ The placement of drugs into higher tiers is intended to encourage patients to try cheaper, generic drugs and avoid the use of what a payer may consider non-essential medications. However, in practice this often results in "step therapy," where a patient must first try one or more less expensive drugs that are often less effective, rather than receiving the drug prescribed by their medical professional. For the sickest patients or those who have conditions such as macular degeneration where additional damage is irreversible, this creates a "double-jeopardy scenario" wherein the sickest patients are forced to bear the largest financial burden due to the required cost-sharing of the drugs in progressively higher tiers. Ultimately, the decision for medical appropriateness should be made by a patient and their physician, rather than a contracted PBM engaged strictly to save costs.

⁶ The IQVIA Institute. "Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023 Institute Report." 9 May 2019. <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>

⁷ Chandra, Amitabh, et al. "The Health Costs of Cost-Sharing." National Bureau of Economic Research. 8 Feb 2021. www.nber.org/papers/w28439.

⁸ Alliance for Aging Research. New Poll Highlights Seniors' Priorities and Concerns in Prescription Drug Pricing Legislation, Misalignment with Congress on Definition of Negotiation. 22 Sept 2021. <https://www.agingresearch.org/news/new-poll-highlights-seniors-priorities-and-concerns-in-prescription-drug-pricing-legislation-misalignment-with-congress-on-definition-of-negotiation/>

⁹ Cubanski, Juliette; Koma, Wyatt; and Neuman, Tricia. "The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019." Kaiser Family Foundation. 1 Feb 2019. <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/>

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Additional costs are also built in by PBMs elsewhere in the system. In 2018, Ohio's Medicaid program commissioned a third-party audit of PBM performance in the state. The audit reported an 8.8 percent difference between the amount PBMs billed to Medicaid managed care plans and the amount paid to pharmacies, amounting to \$223.7 million of PBM revenue in that year.¹⁰ This is a predatory pricing model called spread pricing, and illuminates a problem that exists system-wide that adds additional costs to the prescription drug supply chain.

Exacerbated access issues in underserved communities

Reimbursement rates to pharmacies from PBMs have been steadily declining over time, often to the point that PBMs reimburse pharmacies below their actual cost of acquiring the medication. This practice unfairly impacts independent community-based pharmacies, both urban and rural, that provide more hands-on service to older adults and people with disabilities.¹¹ Low reimbursement also impacts independent pharmacies' long-term viability.¹² These pharmacies often have first-hand knowledge of their customers' personal health issues, and take extra care to review possible drug interactions and which inert ingredients may cause complications for certain patients. The lack of competitiveness that has arisen from PBMs underpaying these small independent pharmacies, or restricting patients from utilizing them, directly impacts the patient by further endangering access to affordable medications.

Recommended reforms for additional study

The Alliance recommends that the federal government follow the example set by Ohio and use an empirical approach to understand the cost of spread pricing across the biopharmaceutical industry, as well as evaluate transparent pass-through pricing models for PBMs. In these models, plans pay the PBM the exact amount paid to the pharmacy for a prescription drug—and “pass-through” the savings from rebates to consumers. Such pass-through models pass on 100 percent of rebates and discounts because their revenue source is a flat administrative fee. This practice forces plans to provide full transparency in their rebate systems, increasing accountability while lowering costs to consumers. The Alliance supports mandating greater PBM and insurer transparency, which is supported by 89 percent of adults aged 60 or older.¹³

¹⁰ Royce, Trevor J et al. “Pharmacy Benefit Manager Reform: Lessons From Ohio.” JAMA vol. 322,4. 23 Jul 2019. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7251257/>

¹¹ Salako, Abiodun; Ullrich, Fred; and Mueller, Keith. “Update: Independently Owned Pharmacy Closures in Rural America 2003-2018.” RUPRI Center for Rural Health Policy Analysis. July 2018. <https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf>

¹² Guadamuz, Jenny; Alexander, Caleb; Zenk, Shannon; and Qato, Dima. “Assessment of Pharmacy Closures in the United States From 2009 Through 2015.” JAMA Internal Medicine. 21 Oct 2019. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2753258>

¹³ Alliance for Aging Research. New Poll Highlights Seniors' Priorities and Concerns in Prescription Drug Pricing Legislation, Misalignment with Congress on Definition of Negotiation. 22 Sept 2021. <https://www.agingresearch.org/news/new-poll-highlights-seniors-priorities-and-concerns-in-prescription-drug-pricing-legislation-misalignment-with-congress-on-definition-of-negotiation/>

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In Ohio, to make up for the lost revenue to companies as a result of reforms directed at the practice of spread pricing, an administrative fee and a dispensing fee were paid to the PBMs. Ohio also implemented a policy mandating that state officials and third-party auditors monitor drug pricing.¹⁴ The Alliance believes that these practices should be considered for wider implementation if they succeed in achieving the goal of increased market transparency and consumer access.

Further, the Alliance maintains that incentives in our healthcare payment systems should reward patient-centered outcomes, rather than be based solely on the volume of services. It would be better for patients if PBMs shifted to a financial model not built on discounts and rebates, but rather on driving improved clinical outcomes. This would spur several important changes in how drug costs and rebates are approached systematically, including driving clinically appropriate utilization of medications, ensuring truly low net costs that benefit consumers rather than driving higher rebates, protecting government budgets, spurring research into underinvested health conditions, and encouraging all members of a care team to work together to ensure best patient outcomes. The current PBM model earns the PBM more money than it saves consumers; a system based on clinical value-added ensures that PBMs are incentivized to take care of patients.

Lastly, the Alliance believes that the FTC should work to combat vertical integration in the PBM market. The three largest PBMs now process nearly 80 percent of all prescription claims in the United States. PBMs argue that mergers help consumers by lowering costs, but there is little evidence to prove that is the case. According to a 2019 study by Short and Ho, “increased market concentration is strongly associated with reduced quality across all patient satisfaction measures.”¹⁵ Further, lack of competition exacerbates issues around rebates and network adequacy in local communities.

Conclusion

At present, PBMs have too much power over patient outcomes and treatment decisions with little oversight or transparency. Allowing this to continue unchecked creates significant burden on consumers and takes medical autonomy away from patients and physicians. Practices such as the use of spread pricing, discrimination against independent pharmacies, and an overinflated market share have created a system in which patients do not have the choices they need to ensure that they are receiving the best care. It is our hope that the FTC will examine these harmful business practices and enact regulatory reforms to permanently curb them.

¹⁴ Royce, Trevor J et al. “Pharmacy Benefit Manager Reform: Lessons From Ohio.” JAMA vol. 322,4. 23 Jul 2019.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7251257/>

¹⁵ Short, Marah Noel and Vivian Ho. “Weighing the Effects of Vertical Integration Versus Market Concentration on Hospital Quality.” Medical Care Research and Review, vol. 77,6. 9 Feb 2019.

<https://journals.sagepub.com/doi/10.1177/1077558719828938>

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Thank you for the opportunity to comment on this issue. If you have any questions, please contact Adina Lasser at alasser@agingresearch.org. We look forward to working with you.

Sincerely,

Beth Mathews-Bradshaw

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