

June 1, 2023

TK Keen, PBM Subgroup Chair

Submitted via electronic mail: jmatthews@naic.org

RE: NAIC PBM Subgroup Draft PBM Whitepaper

Dear Chairman Keen,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), thank you for the opportunity to comment on the April 16, 2023 PBM Whitepaper draft. We are appreciative both of your continued engagement, as well as the Subgroup's, on issues regarding the pharmacy benefit manager (PBM) industry and its place in the health care supply chain.

During our August 2022 presentation as well as in subsequent meetings with committee members, we outlined how considerable market consolidation, lack of transparency, and misaligned incentives within the PBM industry and its interaction with the pharmaceutical supply chain greatly contribute to patient affordability issues within the health care system. As the Subgroup and the National Association of Insurance Commissioners (NAIC) continue discussions on the PBM industry, we reiterate those important themes as well as policy solutions that we believe should be considered. The great work the Subgroup has done on the Whitepaper should be the beginning and not the end of the discussion.

Market Consolidation

PhRMA is increasingly concerned that the substantial rebates, discounts and other payments made by pharmaceutical manufacturers, approximately \$256 billion in 2022,¹ often do not make their way to patients in the form of lower out-of-pocket costs at the pharmacy counter. Insurers, often by way of PBMs, increasingly shift the cost of medicines to patients through deductibles and coinsurance, which expose patients to the undiscounted list price of a medicine.² As you are aware, situated between the biopharmaceutical companies that research and develop innovative medicines and the patients likely to benefit from those treatments, PBMs play a central role in controlling prescription medicine access and affordability for hundreds of millions of Americans. Through horizontal and vertical integration, PBMs' role in the prescription drug supply chain has grown, as has their influence over which medicines patients have access to and whether they are affordable for patients. Moreover, the amount and proportion of value extracted out of the health care system, often through fees retained by these vertically integrated intermediaries, has risen dramatically. This is compounded by the fact that negotiating powers are becoming increasingly concentrated

¹ Fein, A. "The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2023.

² PhRMA. "Deductibles and coinsurance drive high out-of-pocket costs for commercially insured patients taking brand medicines." November 2022. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/G-I/IQVIA-Report-High-OOP-for-Brand-Medicines_November-2022.pdf.

among a small number of large corporations, with the three largest PBMs controlling 79% of all prescriptions filled in the U.S.³

These vertically integrated organizations have enormous influence over which medicines patients have access to, the circumstances under which those medicines are covered, when and where they can be dispensed or administered to patients, and the amount patients are required to pay out of pocket. They comprise some of the largest companies in the U.S. All three of the largest PBMs, or their parent company, are ranked among the top 15 on the Fortune 500 list for 2022, and their combined average annual revenues are nearly four times greater than the combined average for the three largest pharmaceutical manufacturers.⁴

Despite their considerable market power, the top three PBMs have also launched “contracting entities” to further increase negotiating leverage, raise existing fees, and charge a range of new fees.⁵ These PBM contracting entities, or group purchasing organizations (GPOs), introduce an additional non-transparent layer to the pharmaceutical supply chain, which drives up costs without any direct patient benefit. Additionally, two of the three contracting entities are based internationally, creating large corporate tax advantages for PBMs. During a recent investigation, the Senate Finance Committee observed that Ascent Health Services, Express Scripts’ contracting entity, “may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss-based group purchasing organization.”⁶

This market concentration has sparked national attention and inquiries from government entities like the Federal Trade Commission (FTC). In June 2022, the FTC announced that it was launching an investigation into the PBM industry to scrutinize the impact of vertically integrated PBMs on the affordability of and access to prescription drugs.⁷ In addition to immense market consolidation, PBMs currently operate almost entirely in a black box which often prevents health plans, employers, and patients from uncovering the conflicts of interest that riddle PBM decision-making.⁸ And when policymakers do get close to reigning in unfair practices, that black box allows them to “shape-shift” into other entities in order to evade regulation (e.g., creating foreign-based contracting entities). Taking further steps to shed light into the darkness, on May 17, 2023, the FTC announced it had issued two additional compulsory orders to contracting entities connected with CVS Caremark, Express Scripts, and Prime Therapeutics as part of their investigation into this middlemen industry.⁹

PhRMA is supportive of transparency throughout the entirety of the supply chain and is supportive of the NAIC development of an informational resource such as the PBM Whitepaper. Inquiries from your state insurance departments, in conjunction with large scale investigations like the FTC’s, can set the stage for much needed transparency in this portion of the health care system.

³ Fein, A. “The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,” Drug Channels Institute. March 2023.

⁴ The Fortune 500 – 2021 Fortune 500 Company List. <https://fortune.com/fortune500/>.

⁵ Nephron Research. Optum Launches ‘Emisar’ Contracting Entity; Navitus Aligns with Ascent vis Prime. July 26, 2021.

⁶ Senate Finance Committee. Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, January 2021.

⁷ Federal Trade Commission. “FTC Launches Inquiry Into Prescription Drug Middlemen Industry.” Press Release, June 7, 2022.

⁸ U.S. Senate Committee on Commerce, Science, and Transportation. <https://www.commerce.senate.gov/2022/5/cantwell-calls-for-shining-a-light-on-black-box-in-prescription-drug-pricing-market>. May 6, 2022.

⁹ Federal Trade Commission. “FTC Deepens Inquiry into Prescription Drug Middlemen.” Press Release, May 17, 2023.

Misaligned Incentives

A lack of transparency into PBM practices has led to misaligned incentives that can increase costs throughout the health care system. PBMs leverage their control over the market to demand favorable contracts with manufacturers at the expense of patients. According to the Senate Finance Committee, “[m]anufacturers have a strong financial incentive to gain access to a plan sponsor’s formulary, particularly national formularies administered by the three largest PBMs on behalf of hundreds or thousands of health plan clients.”¹⁰ PBMs’ tremendous bargaining power often allows them to dictate terms of contracts with manufacturers and extract large and growing rebates and fees without direct benefit to patients.

Historically, PBMs often retained a portion of the rebates they negotiated on behalf of their commercial health plan and employer clients, denominated as a portion of a medicine’s wholesale acquisition cost (i.e., list price), as compensation for their services.^{11,12} In addition, the administrative fees that PBMs charge to plan sponsors and pharmaceutical manufacturers are commonly based on a percentage of the list price and are usually retained in total by the PBM. Because rebates and administrative fees paid to PBMs are calculated typically as a percentage of a medicine’s list price, government agencies, economists, and other experts have noted that PBMs may favor medicines with high list prices and larger rebates to maximize their revenue.^{13,14}

Public sources have also noted that manufacturer efforts to reduce list prices have been met with significant headwinds, including demand letters from PBMs requiring additional payments in the event of list price decreases.^{15,16} The U.S. Department of Health and Human Services Office of Inspector General (OIG) has also indicated that PBMs may have incentives to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred cost sharing tier, both of which may result in higher costs for patients.¹⁷ PBMs are actively leveraging their market power to bully other entities within the system purely for their own profits and without clear benefits for patients.

¹⁰ Senate Finance Committee. “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,” 2021.

¹¹ PBM Accountability Project. “Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers,” December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true.

¹² Any retention of rebates by PBMs would occur after the rebate is provided by the manufacturer at the sole discretion of PBMs and payers. Such arrangements typically are not transparent to manufacturers.

¹³ 84 Fed. Reg. at 2341.

¹⁴ Medicare Payment Advisory Commission. “Report to the Congress: Medicare Payment Policy. Chapter 13: The Medicare Prescription Drug Program (Part D): Status Report.” March 2021. <https://www.medpac.gov/document/chapter-13-themedicare-prescription-drug-program-part-d-status-report-march-2021-report/>.

¹⁵ Sagonowsky E. “UnitedHealthcare demands drug rebates even if pharma cuts list prices: analyst,” February 2019. <https://www.fiercepharma.com/pharma/letter-to-pharmas-unitedhealthcare-seeks-to-protect-drug-rebates-from-pricereductions>

¹⁶ Gal A, Wilkes L, Chen A, et al. “Biopharma and managed care: UNH reaches out to pharma to manage rebate change, but change is hard and pain will spread.” Bernstein Research. February 8, 2019.

¹⁷ Health and Human Services Office of Inspector General. “Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.” 84 Fed. Reg. 2340 (November 20, 2020). <https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-forrebates-involving-prescription-pharmaceuticals>.

PBMs and Pharmacies

PBMs leverage their market power to craft favorable contracts at the expense of pharmacies and patients. PBMs heavily influence the net revenue a pharmacy will realize for each prescription filled.¹⁸ Market power allows PBMs to craft extraordinarily favorable agreements with pharmacies to capture a significant share of pharmacies' would-be dispensing margins. For example, PBM and pharmacy contracts often include "performance" clauses so that a pharmacy receives an additional payment for exceeding a pre-specified metric or is required to return a portion of their payment to the PBM if they underperform. In practice, however, the payments from pharmacies to PBMs have far exceeded the payments to pharmacies from PBMs.¹⁹ This suggests PBMs are able to compel pharmacies to agree to unrealistic performance metrics, which provide PBMs another avenue to collect additional revenue from pharmacies.

Industry analysts also have noted that many PBM contracts lack uniform definitions, giving PBMs a great deal of flexibility to interpret contract terms in their favor and further contribute to the unequal bargaining power in contract negotiations between PBMs and pharmacies, as well as with employers and other payers.^{20,21} PBMs appear to take advantage of this lax oversight and the absence of industry standards to modify and adjust contracts as needed to mitigate the effects of unfavorable restrictions or reforms. For example, following the passage of state maximum allowable cost (MAC) laws, research shows that PBMs increased their use of effective rate guarantees, which enable PBMs to collect retroactively the spread between the amount paid to the pharmacy and the amount reported to the health plan, while still claiming to operate a pass-through pricing model.^{22,23}

Patient Impact

PBM formulary decisions and utilization management restrictions can influence which medicines patients can access, and when. The formularies that PBMs establish for their clients govern which medicines are covered, the associated patient cost sharing, and any utilization management or other restrictions on their prescribing or use. PBMs may use a variety of utilization management techniques to direct patients and providers towards their preferred medicines, including:

¹⁸ Mulcahy AW, Kareddy K. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." ASPE, October 2021. <https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf>.

¹⁹ Centers for Medicare & Medicaid Services. "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency." Final Rule. May 9, 2022. <https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf>.

²⁰ PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true

²¹ Herman B. "The biggest PBMs are handling more and more of the country's drug price negotiations. STAT+. March 22, 2021. <https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/>.

²² PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true.

²³ Frier Levitt, LLC and Community Oncology Alliance. "Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers." February 2022. https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.

- Prior authorization – the PBM requires the provider to seek approval to prescribe a medicine by submitting documentation to prove that a particular medicine is being prescribed consistent with the PBM’s own established clinical criteria or is medically necessary for an individual patient.
- Step therapy – patients must fail on one or multiple alternative drugs before the PBM will cover the medicine originally prescribed by the provider.
- Formulary exclusions – a medicine is not on the list of drugs typically covered by the PBM.

The past decade has seen a proliferation in the number of medicines excluded from PBM formularies. Formulary exclusions significantly increase PBMs’ negotiating leverage with manufacturers.²⁴ According to the Senate Finance Committee, “[p]harmaceutical companies are sensitive to the sheer size of PBMs and the resulting product volumes they can affect, which allows the middlemen to extract higher rebates from manufacturers through the use of formulary exclusion tactics.”²⁵ The practice of formulary exclusions began in 2012, when CVS Caremark became the first PBM to exclude a subset of medicines from its standard commercial formulary. Express Scripts and OptumRx followed in 2014 and 2016, respectively.²⁶ In 2022, nearly 1,156 unique medicines were excluded from at least one of the three largest PBMs’ standard formularies, a 961% increase since 2014.²⁷

Additionally, PBMs use their consolidated market power and narrow pharmacy networks to steer patients toward affiliated or preferred retail pharmacies. Traditionally, health plans offered unrestricted access to retail pharmacies and patient cost sharing did not vary based on the pharmacy that filled the prescription. Over the past decade, PBMs have implemented narrow networks that incentivize or require patients to fill prescriptions at specific pharmacies that are either affiliated with the PBM or that agree to accept lower reimbursement rebates as a condition of network participation.²⁸ There are two types of narrow pharmacy networks:

- Preferred pharmacy networks, where patient cost sharing is lower at in-network pharmacies compared to out-of-network pharmacies.
- Closed pharmacy networks, where patients are required to use in-network pharmacies or preferred distribution formats (e.g., mail order pharmacy for maintenance or specialty medicines) for their treatment to be covered by insurance.

Pharmacy networks limit patient choice of pharmacies while enabling PBMs to capture larger margins on each prescription filled. Pharmacies that reject low reimbursement rates or other PBM contract terms face exclusion from networks that serve a large share of the market. Currently, 98 percent of Medicare Part D prescription drug plans (PDPs), 52 percent of Medicare Advantage prescription drug plans (MAPDs), and 41 percent of large commercial plans have adopted a

²⁴ Fein AJ. “The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.” Drug Channels Institute. March 2023.

²⁵ Senate Finance Committee. “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,” 2021. [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

²⁶ Xcenda. “Skyrocketing Growth in PBM Formulary Exclusions Continues to Raise Concerns About Patient Access,” May 2022. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.

²⁷ Ibid.

²⁸ Fein AJ. “The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.” Drug Channels Institute. March 2023.

preferred pharmacy network.²⁹ The lack of transparency and accountability within the PBM industry has resulted in a shell game for a PBM windfall that leaves patients and their access to lifesaving medications as an afterthought.

Patient-Centered Solutions

We do not want to come to NAIC and the PBM Subgroup with only concerns; we also have researched and developed patient-centered policy solutions we believe will address many of the misaligned incentives in the system. As an industry, we support ways to enhance competition to drive lower costs. Our companies continue to pay billions in rebates and discounts negotiated with insurers and PBMs.³⁰ We believe that patients need lower out-of-pocket costs without a reduction in health care choice, quality, or access. There is a flaw in the system when rebates and discounts continue to grow without any meaningful benefit directly to patients taking those medicines. PhRMA proposes the following policy solutions to help make medicines more affordable and the system work better for patients:

Share the Savings. Health insurance companies and PBMs often receive sizeable rebates from brand pharmaceutical manufacturers.³¹ On average, more than half of spending on brand medicines is retained by health insurers, PBMs, the government and others in the pharmaceutical supply chain.³² At the same time, many patients are being forced to pay more out of pocket for their medicines due to an increase in deductibles and the use of coinsurance. When patients are facing deductibles or coinsurance, the amount they must pay is often based on the full undiscounted list price of the medicine – even though their insurance company and PBM are paying the discounted amount they negotiated with the manufacturer. States should implement policies to require that savings generated by rebates are passed through to patients at the pharmacy counter.

Delinking Compensation from the Price of a Medicine. “Delinking” PBM compensation from the price of medicines prevents PBMs from skirting regulation on rebates. Rather than receiving compensation based on the price of a medicine, supply chain entities should receive a fixed fee based on the value of the services they provide.

Duty of Care. Expressly imposing a duty or standard of care on PBMs and requiring these companies to act in the best interest of their clients (health plans), providers, and patients—and when in conflict, the patient first—would be an important step for state legislatures to take so that PBMs act in a transparent manner and place their duties to patients, providers, and their clients before their own financial interests.

Anti-Steering. Prohibiting PBMs from directing patients to affiliate pharmacies can improve competition and reduce incentives for PBMs to self-deal. Anti-steering addresses a portion of the vertical and horizontal integration, allowing independent pharmacies a chance to compete and providing patients with access and choice for fulfilling their prescriptions.

²⁹ Ibid.

³⁰ Ibid.

³¹ Fein, A. “The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers,” Drug Channels Institute. March 2023.

³² Berkeley Research Group. The Pharmaceutical Supply Chain, 2013-2020. January 7, 2022.

Moving Forward

NAIC has taken great steps toward addressing issues that impede patients from accessing medicines with the creation of the PBM Subgroup and the subsequent development of the PBM Whitepaper.

PhRMA is supportive of NAIC's effort to shine light on an otherwise murky element of the health care system and has proposed possible policy solutions with immediate impacts. Thank you again for the opportunity to comment and for your consideration of the concerns and solutions outlined within this letter. PhRMA is here as a resource for NAIC and the Subgroup, and we look forward to continued engagement.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. Johnson', written in a cursive style.

Charise Johnson
Director, State Policy
PhRMA