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Administrative State, Regulatory Reform, and Antitrust

The Role of Pharmacy Benefit Managers: Market Power, Pricing Practices, and Policy Implications

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Key Points:

- **The PBM industry is highly concentrated and vertically integrated:** Three PBMs control about 80% of the market, raising concerns about limited competition and innovation. Major PBMs are part of conglomerates including insurers, pharmacies, and healthcare providers, creating potential conflicts of interest and opportunities for self-dealing.
- **This market structure allows for problematic drug pricing practices:** PBMs often increase costs for generic drugs, inflate brand drug list prices through the rebate system, steer patients to higher- rather than lower-cost drugs, and engage in opaque spread pricing. These practices obscure drugs' true costs and lead to higher drug expenditures.
- **PBMs' unique market powers can impact patient access to medications:** PBMs are increasingly restricting patient access to therapies through utilization management policies like prior authorization and formulary exclusions.
- **As a result, many stakeholders are negatively impacted:** These practices negatively affect federal programs, employers, consumers, and uninsured individuals by increasing costs and potentially reducing access to medications.
- **Policy recommendations:** Suggestions include increasing transparency, reevaluating the rebate system, scrutinizing vertical integration, and better aligning PBM incentives with patient and payer interests.

Chairman Massey, Ranking Member Correa, and Honorable Members of the Subcommittee, thank you for the opportunity to testify today about the role of pharmacy benefit managers (PBMs) in our healthcare system. My name is Karen Van Nuys, and I am an economist and Senior Scholar at the Leonard D. Schaeffer Center for Health Policy & Economics, where I also direct the Value of Life Sciences Innovation research program. The opinions I offer today are my own and do not represent the views of the University of Southern California or the USC Schaeffer Center.

The central theme of my testimony today is that while PBMs play a crucial role in our pharmaceutical distribution system, the industry's current structure and practices raise significant concerns about market power, pricing distortions, and misaligned incentives. These issues ultimately lead to higher costs for patients, employers, and taxpayers, while stifling competition in the healthcare sector and impacting patient access to the medications they need.

Background on PBMs

PBMs emerged as simple claims processors in the 1960s but have evolved to become key intermediaries in the pharmaceutical supply chain. Today, they manage drug benefits for health plans and employers, negotiate rebates with manufacturers, design formularies, develop and maintain pharmacy networks, and process prescription claims. This evolution has been marked by significant consolidation and vertical integration with other parts of the healthcare value chain, fundamentally changing the industry's dynamics.

Over the last several decades, PBMs have dramatically increased their size and leverage. Today, just three PBMs handle about 80% of prescriptions filled in the U.S. (1), and all three are vertically integrated with large insurers, specialty pharmacies, mail-order pharmacies, rebate aggregators, and healthcare providers. (2) Some also include retail pharmacies and drug repackaging and marketing subsidiaries. In fact, the top three PBMs are part of companies that rank #4, #6, and #16 on Fortune's list of the largest public companies in America. (3) Together, they account for nearly \$1 trillion in revenues, or 21% of US healthcare expenditures. (4)

This concentration of market power combined with extensive vertical integration raises significant concerns. While PBMs' scale helps them negotiate with drug manufacturers, and their integration could theoretically produce efficiencies, these characteristics also enable them to potentially suppress competition and discourage new, innovative market entrants. The implications of this market structure extend far beyond the PBM industry itself, affecting drug prices, patient access, and overall healthcare costs.

Key Concerns About PBM Practices

Our research at the Schaeffer Center has identified several concerning practices that stem from PBMs' market power and positioning:

1. Increasing generic drug costs

One might expect that PBMs' negotiating power would lead to lower drug prices across the board. However, our research finds this is not the case, with specific evidence from the generic drug market. A study we published in JAMA Internal Medicine in 2021 found that Medicare could have

saved \$2.6 billion in 2018 on just 184 common generic drugs if they had been purchased at Costco cash prices instead of through Medicare Part D plans. Remarkably, involving the PBM and health plan increased average costs by 21%. (5)

This finding is particularly troubling because generic drug markets are intended to be a corner of our pharmaceutical system where competitive forces are harnessed to bring drug prices down. The Hatch-Waxman Act explicitly held out the promise of inexpensive generics to justify the patent protections it granted to brand-name drugs. If PBMs are inflating the cost of generics, it undermines this fundamental tradeoff in our drug pricing system.

2. Increasing brand drug list prices through the rebate system

For competitive classes of brand-name drugs, PBMs negotiate confidential rebates with manufacturers in exchange for preferred formulary placement. While this might seem like it would lower costs, in practice we've seen it create perverse incentives that lead to higher list prices: as manufacturers compete for better formulary positions by offering PBMs bigger rebates, list prices rise to accommodate those higher rebates.

Our research on insulin prices illustrates this dynamic. We found that between 2014 and 2018, insulin list prices rose 40% while net prices received by manufacturers fell 31%. Importantly, those savings that PBMs were negotiating from manufacturers did not translate into lower overall expenditures per unit of insulin – instead, they were absorbed by PBMs and other distribution intermediaries. During this period, the share of insulin spending captured by PBMs and other intermediaries more than doubled, from \$31.29 out of every \$100 spent on insulin in 2014 to \$53.27 in 2018. PBMs' share alone grew 155%, from \$5.64 to \$14.36. (6)

This perverse dynamic doesn't just affect insulin. A 2021 study by my Schaeffer colleagues published in JAMA Network Open found that the most competitive drug classes feature the fastest growth in list prices. List prices grew 11.1% annually for off-patent drugs with multiple molecules in the same class, compared to 10.8% for on-patent drugs in single-molecule classes and 9.3% for on-patent drugs in multi-molecule classes. (7) This counterintuitive result – higher list price growth in more competitive markets – illustrates the perverse incentives created by the current system of confidential rebates.

3. Steering patients to higher- rather than lower-cost drugs

The rebate system not only inflates list prices but can also lead PBMs to steer patients to more expensive drugs through their coverage policies. There are numerous examples of PBMs giving more favorable formulary placement to expensive brand-name drugs over lower-cost generics or biosimilars, likely due to the larger rebates offered on the higher-priced products. Humira biosimilars provide a recent example: although biosimilars became available in early 2023, CVS Caremark did not exclude the originator Humira from most of its commercial formularies until April 2024.¹ (8) During that delay, the PBM was continuing to collect the rebates on the originator product. And such examples are not occasional anomalies: a study of Medicare Part D formularies found that 72% of them placed at least one branded product in a lower cost-sharing tier than its generic equivalent. (9)

¹ After excluding Humira, the preferred adalimumab options included Hyrimoz, a biosimilar version jointly marketed through its own subsidiary, Cordavis.

This practice can significantly increase costs for both patients and the healthcare system as a whole. It also undermines the cost-saving potential of generic and biosimilar competition, potentially discouraging investment in these lower-cost alternatives.

4. Hiding PBM compensation through spread pricing

Another practice that has received much attention is spread pricing. Spread pricing occurs when PBMs charge health plans more for a drug than they reimburse pharmacies, pocketing the difference. The health plan doesn't see what the pharmacy is paid, so does not know how much spread the PBM is pocketing. As a result, the plan lacks a clear understanding of the full amount it is paying for PBM services. In 2018, a state audit in Ohio found PBMs charged 31% average spreads for generic drugs in its Medicaid managed care system. (10) In response, the Ohio Department of Medicaid moved to a single PBM to administer managed care drug benefits, and eliminated the opaque practice of spread pricing. This practice not only increases costs for health plans and taxpayers but also puts financial pressure on pharmacies, especially smaller independent ones.

5. Collecting copayments exceeding the cost of the drug

While now somewhat restricted by federal gag clause legislation, the practice of copay clawbacks illustrates how PBMs have historically leveraged opaque pricing against patients' interests. We found that in 2013, 23% of prescriptions in a commercial claims dataset involved a patient copay that exceeded the total cost of the drug to the PBM, with the PBM keeping the overpayment. When an overpayment occurred, it averaged \$7.69 per claim. (11) Before they were outlawed, gag clauses in contracts between PBMs and pharmacies would prohibit pharmacists from telling patients when their copayment was more than the cash price for the drug.

6. Restricting access

Over the last decade, PBMs have increasingly restricted patients' access to therapies through utilization management policies like prior authorization, step therapy and formulary exclusions. In a recent study of Medicare Part D plan formularies, my colleagues and I found that the share of compounds restricted in non-protected classes rose from an average of 31.9% in 2011 to 44.4% in 2020. (12) Formulary exclusion, the most extreme form of utilization management, has been imposed especially aggressively: By 2020, Medicare plan formularies excluded an average of 44.7% of brand-name-only compounds. Interestingly, drug formularies for Medicare Advantage plans, which are also responsible for patients' hospital and other medical costs, were significantly less restrictive than those for standalone Medicare drug plans. While formulary management to encourage therapeutic competition makes sense, such aggressive utilization management may come at the expense of higher medical expenditures.

These practices, taken together, paint a picture of an industry that has used its market power and unique position in the pharmaceutical supply chain in a way that raises rather than lowers costs for patients, taxpayers, and other stakeholders in the healthcare system.

Horizontal and Vertical Integration

The concerns raised by PBM practices are amplified by the industry's high level of both horizontal and vertical integration.

Horizontal integration in the PBM industry has resulted in just three companies controlling about 80% of the market. (1) Using national retail prescription data from 2023, Schaeffer researchers found that market concentration levels exceed the Department of Justice's and Federal Trade Commission's threshold for "highly concentrated" markets overall and by payer type: commercial, Medicare Part D, and Medicaid managed care insurance. (13) This high level of concentration raises concerns about limited competition and innovation in the PBM market itself. Indeed, these concerns were raised in 2012 when the Federal Trade Commission investigated but ultimately declined to block the merger between two of the three largest PBMs, Express Scripts and Medco Health Solutions. (14) At the time, a dissenting opinion expressed one commissioner's belief that the merger would have anticompetitive effects, and called on the Commission to, in three years' time, "conduct a thorough analysis of this industry to determine if prices to employers in fact have gone down....I believe—with deep sadness and concern—that will not prove to be the case." (15) While no analysis was conducted after three years, that belief now seems prescient.

Vertical integration adds another layer of complexity. The largest PBMs are now part of conglomerates that include health insurers, specialty pharmacies, mail-order pharmacies, healthcare providers, and rebate aggregators. (2) In some cases, PBMs are part of corporate families that include retail pharmacy chains and subsidiaries that commercialize, market and distribute drug products. This integrated architecture creates many potential conflicts of interest and opportunities for anti-competitive behavior. For example:

- A vertically integrated PBM can steer the most profitable prescriptions to their affiliated pharmacies (16), or steer patients to their own mail-order pharmacy, as suggested by evidence in recently released reports from both the FTC and House Oversight Committee. (17,18)
- An insurer in a vertically integrated company can use spread pricing to shift profits into its affiliated PBM or pharmacy to avoid the medical loss ratio restrictions imposed by the Affordable Care Act. (19)
- A vertically integrated PBM can prefer the biosimilar marketed by its own subsidiary on its formularies over one that is lower cost, thereby blocking competition from other biosimilar manufacturers and raising overall costs. (8)
- A vertically integrated company may negotiate manufacturer rebates through its offshore GPO, thereby shielding those rebates from U.S. transparency requirements and regulatory scrutiny. (18)

Thus, both horizontal and vertical integration allows these companies to leverage their market power across multiple segments of the healthcare system. This can create barriers to entry for potential competitors and may enable anticompetitive practices that are difficult to detect due to the opaque nature of PBM contracts and pricing.

Impacts of Inefficiencies in the PBM Market

Our research suggests that excessive PBM market power has significant adverse impacts on various healthcare system stakeholders:

- **Federal programs:** Medicare and Medicaid are overpaying for drugs, particularly generics, due to PBM practices. (5) This increases costs for taxpayers and threatens the sustainability of these crucial programs.
- **Employers:** Lack of transparency in PBM contracts and misalignment of incentives between PBMs and their clients make it difficult for employers to assess whether they're getting value for money, potentially leading to higher healthcare costs for businesses and their employees.
- **Consumers:** Patients face higher out-of-pocket costs due to inflated list prices and unfavorable formulary designs, particularly in high-deductible plans. (20) They also face tightening restrictions on the drugs they can access through insurance. (12) Both can lead to reduced medication adherence and poorer health outcomes.
- **Uninsured individuals:** Those without insurance pay inflated cash prices that reflect inflated list prices and other markups, potentially putting necessary medications out of reach.

Policy Implications and Recommendations

The issues I've outlined today call for serious consideration of policy reforms. While PBMs can and do provide valuable services, the current structure of the industry has created misaligned incentives and opportunities for rent-seeking behavior that increase costs for patients, employers, and taxpayers.

I recommend the following areas for policy consideration:

- 1. Increase transparency:** Require greater transparency to PBM clients of contract terms, rebates, and true net pricing, so that they can better assess the value that PBMs are offering. HHS should also develop and publish high-quality, public benchmarks for average prices, by drug, for key transactions in the supply chain. These benchmarks could be modeled on the existing, publicly-available National Average Drug Acquisition Cost series (NADAC) which was created to help Medicaid programs ensure they are getting fair prices for prescription drugs. A weekly survey is used to understand what pharmacies are paying, on average, to acquire drugs; these averages are published and used as inputs to determine Medicaid reimbursements. A similar process could be used to generate similar benchmarks of what PBMs are paying pharmacies, what they are charging plans, and what they are collecting from manufacturers in rebates and fees. These average benchmarks should be made widely available. Survey responses should be made mandatory to better ensure that data collected is representative and accurate.

Such benchmarks would provide important context for PBM clients to evaluate their PBMs' performance, facilitate price shopping, and intensify competitive pressure on PBM market players. They will also enable policymakers and researchers to identify potential abuses.

- 2. Reevaluate the current rebate system:** The current system of confidential rebates drives up list prices, increases patients' out-of-pocket burden, and distorts market incentives. Policymakers should consider alternatives that better align with patient and payer interests. Patient out-of-pocket expenditures should be based on post-rebate prices.
- 3. Scrutinize vertical integration:** The potential for anticompetitive effects from vertical integration in the PBM industry is significant, and warrants close antitrust scrutiny. Regulators should investigate practices that weaken standalone competitors, such as steering the most lucrative patients or prescriptions to affiliated pharmacies, or giving preferred formulary placement to one's own biosimilar product rather than a cheaper biosimilar from an unaffiliated manufacturer.
- 4. Align incentives:** Explore ways to better align PBM incentives with the interests of patients and payers, including changing how PBMs are compensated, or imposing fiduciary requirements on PBMs.

Conclusion

The pharmaceutical distribution system, with PBMs at its center, plays a crucial role in delivering life-saving medications to patients. However, the current structure of the PBM industry, characterized by high concentration, vertical integration, and opaque business practices, raises significant concerns about its impact on drug prices, patient access, and overall healthcare costs.

Policymakers should consider reforms that will benefit patients and healthcare purchasers, including those that will promote competition, provide information that payers and patients need to make sound economic decisions, and improve patients' access to the treatments prescribed by their doctors. By doing so, we can better harness the potential benefits of PBMs – their ability to negotiate lower prices and manage complex drug benefits – for the benefit of patients and those who ultimately pay for their healthcare: US employers, workers, and taxpayers.

Thank you for the opportunity to testify. I would be happy to answer any questions.

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