



May 24, 2022

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

Re: *FTC-2022-0015-0001 Request for Information: Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers*

Dear Chair Khan:

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. Our work within the health care sector is driven by a recognition that the system costs too much and fails to adequately care for the people it seeks to serve. We prioritize five objectives to make health care more affordable and accessible: lower prescription drug prices; lower excessive commercial sector prices charged by providers; improve provider payment to incentivize the delivery of high-quality and efficient care; ensure Medicare's financial sustainability; and improve care for people with complex care needs.

Our work on prescription drugs focuses on the drivers of high drug and biologic prices and spending: patent abuses and anti-competitive behaviors; market distortions; and high launch prices and unjustified price increases. High prescription drug prices, particularly for brand-name products, pose significant affordability problems for patients, employers, and taxpayers. Arnold Ventures' goal is to promote evidence-based policy solutions that comprehensively lower drug prices while maintaining incentives for meaningful drug innovation.

Arnold Ventures appreciates the opportunity to submit this Request for Information to the Federal Trade Commission (FTC) on the "*Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers*."

Pharmacy Benefit Managers (PBMs) have evolved over the decades from basic claims administrators to more complex organizations offering a wide range of prescription drug management tools, such as drug utilization review, disease management, and consultative services. A key function of PBMs is to negotiate price concessions from pharmacies and brand-name drug manufacturers to lower costs to health plans and employers.

Mergers in the PBM industry (between PBMs as well as between PBMs, insurers and pharmacies) have created a highly concentrated industry. These mergers likely increase drug benefit costs and insurance premiums, as demonstrated in other sectors of health care, such as [mergers between hospitals](#) and between [hospitals and physician groups](#). In addition to being integrated with insurers, the three largest PBMs – CVS Caremark (Aetna), Express Scripts (Cigna), and OptumRx (UnitedHealth Group) – also own their own specialty pharmacies which likely increases drug benefit costs. The effects of this interconnectedness and market concentration on drug benefit costs warrants further study.



Contracting terms between PBMs and their clients lack transparency. Requiring that the clients of PBMs receive all of the rebates negotiated on their behalf and that PBMs report all other payments received from brand manufacturers to their clients would reduce drug benefit costs because increasing transparency enhances competition between PBMs and enables the client to obtain better contract terms. Still, without greater insight into the business practices that PBMs use in their contractual arrangements – targeting policies to fully address transparency issues is not possible.

Put simply, PBM profits increase as rebates increase. This has contributed to the growing gap between list and net prices in the US market, which also [increases](#) beneficiary out-of-pocket (OOP) spending and can lead to access problems.

To be clear, there are several stakeholders throughout the biopharmaceutical supply chain that contribute to high prescription drug prices. Most formidably, pharmaceutical manufacturers can set and perpetually increase their list prices over time. Comprehensive action is needed to:

- Reduce patent abuse and over-patenting practices;
- Strengthen the U.S. Food and Drug Administration's (FDA) approval standards;
- End market distorting practices like manufacturer coupons; and,
- Promote policies to address high launch prices and unjustified price increases while maintaining incentives for meaningful innovation.

That said, FTC is uniquely positioned to unpack the role of PBMs and bring much needed insights into to this segment of the drug supply chain.

The views expressed below are informed by the available body of evidence; however, in each bucket we note that considerable research and empirical evidence is needed to inform ongoing policy discussions. Importantly, most if not all of the considerations below stem from a lack of transparency into PBM practices and market dynamics that must be brought to light to inform a robust discussion and generate evidence-based solutions.

I. Lack of Transparency in Contracting

Due to a complete [lack of transparency in PBM contracting](#), the clients of large PBMs, such as self-insured employers, do not know the actual cost of the drugs that beneficiaries take or how much PBMs are profiting from their business. The smaller the employer or insurer, the less information they are able to obtain from their PBM on the actual costs of drugs purchased by their beneficiaries. In its analysis of the effects of greater transparency in contracting, [CBO concluded](#) that policies that would increase transparency in contracting in this industry would have the greatest benefits for smaller clients of PBMs.

Rebates. PBMs retain a share of the rebates they negotiate on behalf of their clients in addition to receiving fees from manufacturers for other services they provide. But their clients do not have line of sight into those monetary transfers between manufacturers and PBMs. Large PBMs can also hide the rebates that they collect through their own rebate aggregators (or group purchasing organizations (GPOs)). Each of the three largest PBMs has a [rebate aggregator or GPO](#) that negotiates rebates with manufacturers on its behalf. It is possible the PBM's client is guaranteed a 100 percent rebate pass-through while the PBMs own rebate aggregator or GPO (which is a related but separate company) is retaining a share of the rebates and fees collected from manufacturers. The PBMs' clients have no line of sight into how much of the rebates negotiated by the rebate aggregator are passed through to the PBM itself. These rebate aggregators and



GPOs are often [offshore](#) thus avoiding U.S. regulatory scrutiny, and they effectively prevent clients of PBMs from having any way to verify compliance or access reported data.

More specifically, GAO [reported](#) that Medicare Part D plan sponsors received nearly all of the rebates that were negotiated by PBMs on behalf of Part D plan sponsors in 2016. But since that time, use of rebate aggregators and GPOs by large PBMs gained [prominence](#) and may be a method for PBMs to [hide a share of the rebates](#) and fees they collect from manufacturers on drug purchases by Medicare Part D beneficiaries. The growing practice of PBM-owned rebate aggregators and GPOs warrants further study by the FTC in terms of how this practice affects both Medicare and the commercial markets.

Spread Pricing. Another symptom of the lack of transparency is where PBMs pay pharmacies less for prescriptions than what they charge their clients. This is referred to as “spread pricing” and is most common in commercial plans. This practice is especially problematic for generic drugs. Clients may pay a specified percentage off of the list price across all generic drugs while PBMs reimburse pharmacies at a lower maximum allowable cost (MAC) price that is more closely aligned with pharmacy acquisition costs for generic drugs (but has no relationship to the list price).

The clients of PBMs do not know the MAC prices and, therefore, cannot easily assess how much PBMs are profiting from spread pricing. Specifically, PBMs - together with other segments of the supply chain - appear to be profiting off of higher cost generic drugs (see [46 Brooklyn](#)). When Ohio’s Medicaid program was [audited](#), PBMs were found to retain a spread equal to about 30 percent of the cost of generic drugs in one quarter (Medicaid was charged \$663 million for the generic drugs but pharmacies were paid \$208 million less than that amount – which was retained by the PBMs). More recently, in April of this year, the Attorney General of Louisiana [sued](#) the PBM OptumRx for this same practice of spread pricing. Finally, [one study](#) found that Medicare Part D paid \$2.6 billion more for generic drugs relative to prices charged by Costco in 2018—suggesting that PBMs and other participants in the supply chain are overcharging Medicare for these drugs.

This lack of transparency makes it difficult for clients to evaluate the offers from competing PBMs as well as the performance of the PBM that they choose. We believe this secrecy weakens competition between PBMs for clients and contributes to higher PBM profits in this concentrated industry. CBO estimated that if the clients of PBMs received all of the rebates negotiated on their behalf (as well as any fees paid by the manufacturer to the PBM) and if spread pricing were prohibited, commercial sector drug spending would be reduced initially by 1 percent (CBO cost estimate of \$1.895 billion). That amounts to about \$1.4 billion in lower drug spending in 2020 for commercial plans (1 percent of CMS [NHE estimates](#) of drug spending by private health plans).

PBM contracting will adjust to any regulations that are put into place to shed light on monetary transfers, fees and other price concessions they receive. The shift to the use of rebate aggregators, as discussed above, is just one example of this. Another example would be the fluidity of the definition of what constitutes a rebate versus a service fee, which is challenging to regulate.

II. Mergers and Acquisitions



The PBM industry is highly concentrated and its profits have been [increasing](#). The three largest PBMs – CVS Caremark, Express Scripts and OptumRx – now control almost 80 percent of the market and fall within the top 13 [Fortune 500 companies](#). This industry likely grows more concentrated over time in part because larger PBMs have a competitive advantage. Their enormous negotiating power drives larger price concessions from manufacturers and pharmacies relative to smaller PBMs with less market share. Moreover, the FTC’s approval of a merger between two large PBMs (Express Scripts and Medco) in 2012 greatly increased market concentration in this industry.

The consequences of this particular occurrence of market concentration are not well understood. On the one hand, greater market concentration means larger PBMs have increased leverage to obtain price concessions, which could potentially lower insurance premiums to the extent that those concessions are passed on to insurers. But on the other hand, the concentration reduces competition and allows PBMs to retain a larger share of the price concessions as profits. A study by the FTC on this topic is critical to help policymakers understand the effects of market concentration on drug benefit costs and insurance premiums.

PBMs and Insurers. Each of the three largest PBMs has merged with a large health insurer. While some efficiencies could be gained, this leads to higher premiums for some insurers. The merged entity serves health insurers as clients of its PBM but it also competes with those same insurers in the marketplace. (For example, PBMs that both sponsor large Part D plans and serve smaller Part D plan sponsors as clients are an example of this). This [creates an incentive](#) for the merged entity to charge competing health insurers more for its standalone PBM services.

PBMs and Pharmacies. Finally, it is unclear whether the merger between a large PBM and a large chain pharmacy (such as CVS Caremark) is helpful to consumers. While there could be efficiencies gained that lower costs and prices, the merged entity now has a conflict of interest. The merged entity profits as both the volume and price of prescriptions dispensed at its own pharmacies increases. That does not align with its responsibility to lower drug costs for its clients.

The top three specialty pharmacies are each owned by one of the three largest PBMs. Those three specialty pharmacies accounted for [65 percent](#) of total prescription revenues from pharmacy-dispensed specialty drugs in 2021 (and that market concentration is expected to grow in 2022). While specialty drugs make up a small share of prescriptions dispensed, they constitute a [large share](#) of drug spending. Since PBMs’ profits increase as the dollar value of drugs sold through its specialty pharmacy increases – this creates a conflict of interest with its clients.

Moreover, to the extent a PBM is able to negotiate a price concession on a specialty drug from the manufacturer, some of that concession could come through lower acquisition cost to the PBMs’ specialty pharmacy and some could flow through a rebate. The amount that flows through a lower acquisition cost would not be tracked in data accessible to the clients of the PBM. This represents another way that price concessions could potentially flow from the manufacturer to the PBM without being tracked by clients of PBMs or reported as rebates. [MedPAC has raised concerns](#) about the conflicts of interest and lack of transparency that occurs when large PBMs own specialty pharmacies.

III. Drug Pricing and Rebates



Since PBMs retain a share of rebate revenues, PBMs prefer that manufacturers of brand-name drugs give price concessions in the form of rebates, rather than in the form of lower list prices. Manufacturers have responded by increasing both list prices and rebates as they compete for preferred placement on the PBM's formulary. As a result, the gap between list and net prices has grown substantially over time – especially in competitive therapeutic classes where PBMs have more leverage to negotiate for price concessions.

There is plenty of evidence that rebates as a share of drug spending have increased over time. For example, the [Medicare Trustees report](#) documents Medicare Part D rebates – as a share of drug spending – increased from 11.6 percent in 2011 to 26.5 percent in 2019. For large commercial insurers, [one study](#) found that rebates as a share of drug spending increased from 13.6 percent in 2015 to 22 percent in 2019.

Researchers, such as Robin Feldman, have pointed out that [PBMs can appear](#) to be doing a great job for their clients as rebates grow as a share of drug spending, but they are not actually holding down net price growth of brand-name drugs. Because of this information asymmetry, the clients of PBMs may know that rebates are increasing but they are not able to assess how quickly the net prices of brand-name drugs are growing over time. In Medicare Part D, both MedPAC and CBO have found that net prices for brand-name drugs have been growing by more than 7 percent per year. MedPAC found that over the same period (2010 to 2020) list prices grew by 10 percent per year. It is likely that commercial plans have a similar experience since they also rely on PBMs to negotiate net prices on their behalf (although the composition of drugs taken is different). [There is some question](#) as to whether PBMs are really doing a good job on behalf of their clients if the net prices of brand-name drugs are growing so quickly over time.

There are also some instances where PBMs have favored drugs on their formulary that have high list prices and high rebates over drugs with lower net costs. For example, some PBMs cover the brand-name products [Vimovo and Duexis](#) although these drugs simply combine the active ingredients of less expensive generic drugs. This is an example of PBMs [covering](#) brand-name drugs that are likely to have higher rebates even though less expensive generic products could be used.

Within the Medicare Part D program, PBMs facilitated the movement of pharmacy price concessions into a post-point-of-sale transaction, often taking the form of a fee paid by the pharmacy to the plan sponsor at a later date (that fee gets included in what is called “direct and indirect remuneration” (DIR) in Part D). This allowed pharmacy price concessions to be treated in a similar manner as a manufacturer rebate. The cost of the prescription at the pharmacy went up as did out-of-pocket costs. The savings from such pharmacy price concessions lowered net drug costs and premiums but likely also contributed to higher profits for Part D plan sponsors. MedPAC has [expressed concerns](#) that monetary flows through direct and indirect remuneration may be captured in higher profits for Part D plan sponsors. Large PBMs are among the biggest plan sponsors in the Part D program. It is worth noting that a new final rule issued by CMS requiring all pharmacy price concessions obtained by Part D plans be passed through at the point of sale starting in 2024.

IV. Potential Association Between Number of Covered Lives and PBM Negotiated Prices



We also urge the FTC to study the extent to which larger clients of PBMs are charged less for PBM services and pay less for prescription drugs than smaller clients of PBMs. For example, if having more covered lives gives the PBM greater negotiating leverage with pharmacies and manufacturers – this would mean larger clients are more valuable to a PBM because covering their beneficiaries could increase a PBMs' profitability across its entire book of business (by increasing the rebate revenues the PBM is able to retain across all covered lives). The extent to which large clients obtain better terms in their contracts with PBMs and the reasons why this occurs warrants further study by the FTC. It is likely that small insurers and small employers are paying the highest costs for their drug benefits. For example, [one study](#) found that post-rebate drug costs per covered life were 8 percent higher in small group plans compared to large group plans in 2019 (\$796 compared to \$738). That is particularly surprising if large group plans are more likely to offer generous drug benefits.

In addition, large employers may not receive terms from PBMs that are as good as large insurers because they cannot as easily internalize PBM functions. It is telling that over time more and more large insurers either integrated with a large PBM or formed their own PBM. This practice also warrants study by the FTC.

V. Patient Access

PBM incentives are not aligned with patients as high list prices lead to higher OOP costs for beneficiaries in Medicare Part D and less generous commercial plans as well as the uninsured. [Underscored](#) in a recent Senate hearing is the point that as list prices grow faster than net prices, sicker beneficiaries disproportionately subsidize premiums of healthier beneficiaries through higher out-of-pocket costs. This has dramatic implications for health equity. David Balto, in his testimony during the aforementioned hearing, [stated](#) that in its analysis of PBMs to date, the FTC has not examined how PBMs affect the beneficiaries in plans they serve.

Finally, PBMs sometimes obtain rebates by excluding drugs from their formulary. For example, in the case of curative Hepatitis C drugs, some PBMs only included a subset of all the different brand-name drugs available to cure this disease on their formulary while others were [not covered at all](#). This exclusionary practice likely enabled the PBM to obtain steeper rebates on the drugs covered in this class. If the FTC were to study this issue, the question is whether the drugs included on the formulary were sufficiently close substitutes to drugs that were excluded such that the welfare gains from lower net prices (and lower OOP costs and premiums) offset any costs to the beneficiaries resulting from the formulary exclusion. With respect to formulary tiering (lower copayment for preferred brand-name drugs), preliminary work by [Josh Feng](#) found the overall effects of tiering does increase welfare for consumers. But at the time of that study, lower net prices were generally obtained through the threat of exclusion rather than through actual exclusions.

Conclusion

We applaud the FTC for its commitment to protect consumers and competition by preventing anticompetitive, deceptive, and unfair business practices. Additionally, we thank the FTC for the opportunity to comment and for your review. Arnold Ventures looks forward to working with the FTC and the administration to implement policies that encourage innovation while also best serving patients, employers, and taxpayers.



Arnold Ventures is prepared to assist with any additional information needed. Comments were drafted with assistance from Anna Anderson-Cook, Kirk Williamson, and Andrea Noda. Please contact Andrea Noda at anoda@arnoldventures.org with any questions.

Sincerely,

Mark Miller
Executive Vice President of Health Care
Arnold Ventures