PREMIER TRANSFORMING HEALTHCARE TOGETHER®

May 25, 2022

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

Submitted electronically via www.regulations.gov

Re: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers [Docket Number FTC-2022-0015-0001]

Chair Khan:

The Premier healthcare alliance ("Premier") appreciates the opportunity to submit comments to the Federal Trade Commission ("FTC") on the request for comments titled "*Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers [Docket Number FTC-2022-0015-0001]*." FTC is soliciting public comment on how the business practices of pharmacy benefit managers ("PBMs") affect patients, doctors, employers, pharmacies and other businesses in the prescription drug space.

Premier has serious concerns that a lack of transparency and oversight of PBM practices has resulted in several negative consequences for patients and stifled competition. Premier urges the FTC to investigate, under Section 6(b) of the FTC Act, the practices of PBMs and further, to implement transparency standards for PBMs. Specifically, at minimum, Premier recommends that PBM transparency standards:

1. ***Be created to specifically meet the needs of the PBM business model;***
2. ***Require PBMs to report all fees, rebates, discounts, etc. at least annually, including what percentage of fees are passed through;***
3. ***Require PBMs to disclose differential reimbursement for PBM-owned or PBM-affiliated pharmacies;***
4. ***Require PBMs to disclose how pharmacy reimbursement is calculated, maintained, updated, and where to find relief when paid below actual acquisition costs; and***
5. ***Ensure state oversight of Medicaid Managed Care Programs to deter tactics such as spread pricing.***

I. Background on Premier and Group Purchasing Organizations

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,400 U.S. hospitals and health systems and 225,000 non-acute providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables

better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with providers to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of our alliance is our Integrated Pharmacy Program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality, safety and resiliency, and increase knowledge-sharing among healthcare professionals.

Premier has been a leader in implementing and advocating for sustainable market-based solutions to address the rising cost of pharmaceuticals and healthcare. Premier is a leading group purchasing organization ("GPO"), which helps our health systems and other providers leverage their purchasing volume to negotiate competitive prices on healthcare products and services. Nationwide, GPOs serve as a sourcing and purchasing partner to virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. One report estimated that GPOs reduce supply-related purchasing costs by 13.1 percent and will reduce healthcare spending by up to $456.6 billion between 2017 and 2026.[1] Specific to government-sponsored health plans, GPOs generate $8.7 billion annually in Medicare cost-savings and $6.8 billion annually in Medicaid cost-savings; and are estimated to save more than $200 billion over the next ten years in government healthcare spending.[2] The value that GPOs deliver allows healthcare providers and physicians to focus on their core mission: providing first-class patient care.

GPOs are also an extremely transparent segment of the healthcare system as 42 CFR 1001.952(j) requires that GPOs meet the following two standards:

1. The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following:
    - The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of goods or services provided by that vendor.
    - In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of the purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).
2. Where the entity which receives the goods or service from the vendor is a healthcare service provider, the GPO must disclose in writing to the entity at least annually, and to the Secretary of the U.S. Department of Health and Human Services upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

GPO administrative fees average approximately 2 percent.[3] The administrative fee is calculated on the negotiated net price, not the list price. In other words, this price reflects the true price net of any discounts.

[1] Allen Dobson, Steve Heath, Phap-Hoa Luu, Jessica Greene, Joan E. DaVanzo. A 2018 Update of Cost Savings and Marketplace Analysis of the Health Care Group Purchasing Industry. https://www.supplychainassociation.org/wp-content/uploads/2019/05/HSCA-Group-Purchasing-Organizations-Report-FINAL.pdf
[2] *Id.*
[3] GAO-10-738

The use of GPOs is completely voluntary and their contracts are used only if they deliver the best value. A study[4] by a former U.S. Federal Trade Commissioner confirmed that GPOs operate in a highly competitive market with national, regional, and local GPOs competing with each other to reduce costs and deliver high-quality products and services. Furthermore, GPOs also have a robust code of ethics and GPO business practices are revealed on a public website.[5]

The differences in transparency requirements between GPOs, PBMs, and others in the supply chain are further highlighted in Attachment A.

GPO services are transparent and provide incredible value that result in savings for patients, providers, and the government. Therefore, Premier believes that all entities within the healthcare supply chain should be held to similar transparency standards and urges FTC to implement transparency standards for PBMs.

II. PBM Practices Result in Negative Consequences for Patients and Stifle Competition

Over the past decade, certain PBM practices have become more egregious resulting in negative consequences for patients, doctors, employers, pharmacies and other businesses in the prescription drug space. In our comments, we highlight several of these practices and their consequences, but also note that this list is not exhaustive.

- Rebates and Formulary Placement – One tactic that has been used by PBMs to thwart competition is the use of rebates to prefer a brand or biologic product on formulary over a cost-saving generic or biosimilar. In the case of biologics, manufacturers have been offering steep rebates upon market entry of a competitor biosimilar to maintain the biologic as the preferred product on a payor's or PBM's formulary. This discourages adoption of the biosimilar and often prohibits patients from accessing the lower cost biosimilar. In some cases, rebates are thought to help the biologic product maintain upwards of 97 percent of market share years after a biosimilar is available.[6] Ultimately, this practice results in higher cost-sharing for patients and overall higher costs for the healthcare ecosystem in lieu of taking advantage of lower cost generics and biosimilars. It also disincentivizes generic and biosimilar manufacturers from entering the marketplace given the control that PBMs exert over market share due to formulary placement.

- PBM Preferred Products - Another key factor is PBM preference for a single biosimilar and a lack of parity across biosimilars. In comparison, in the brand and generic drug space, if a generic is covered by a PBM, then all manufacturers of the generic drug are typically covered. In the case of biosimilars, many PBMs are selecting only a single biosimilar to place on formulary. This is resulting in the need for pharmacies to create extensive workflows to ensure patients receive the right drug based upon their PBM preference. For example, one Premier hospital has a 30-step workflow process to dispense pegfilgrastim and similarly lengthy workflows exist for each additional biosimilar.

[4] Dan O'Brien, Jon Leibowitz, and Russell Anello, How Group Purchasing Organizations Reduce Healthcare Procurement Costs in a Highly Competitive Market (Jun 2017) https://www.supplychainassociation.org/wp-content/uploads/2018/05/Leibowitz_GPO_Report.pdf
[5] Healthcare Group Purchasing Industry Initiative https://hgpii.com/
[6] https://www.sec.gov/ix?doc=/Archives/edgar/data/200406/000020040619000053/a2q10q06-30x19.htm

Furthermore, PBM preference is inhibiting hospitals and healthcare providers from creating their own institutional formularies. This is resulting in pharmacies being required to carry a biologic and all biosimilars to the reference product. This creates severe inefficiencies for a pharmacy to manage their inventory effectively, especially given the expense of these products and refrigerator space required for storage.

Finally, PBM preference is creating delays in patient care as pharmacists work to understand which product is covered by each patient's individual insurance. This often requires the reissuance of a prescription to align with the exact biosimilar that is covered due to the naming convention and lack of biosimilar to biosimilar interchangeability guidance. As a result, patients may be asked to return to receive their treatment.

- White Bagging and Patient Steering – In a practice known as "white bagging," PBMs determine when, where, and how drugs must be purchased, prepared, and administered to patients – almost always steering these prescriptions to be filled by PBM-owned pharmacies. The drugs are then delivered to the physician for administration to the patient. This practice undermines the ability of a physician or patient to have their prescription filled at a pharmacy of their choosing. White bagging also jeopardizes patient care as prescriptions are often delayed or do not align with updated treatment protocols, especially for oncology patients where treatment may need to be adjusted last minute. Furthermore, patient safety is a major concern as white bagging forces physicians to administer drugs that have been outside of their chain of custody where they cannot confirm if the drug has been stored or prepared safely, yet liability if the patient has an adverse event to the product continues to reside with the administering physician. White bagging also places a tremendous administrative burden on hospitals to reconcile these policies on behalf of their patients.

- DIR Fees - Pharmacy price concessions, known as direct and indirect remuneration ("DIR"), which allow PBMs to claw back dollars from pharmacies, are problematic for beneficiaries, pharmacies and the government alike. DIR fees are extremely impactful to pharmacies that are placed at risk of going out of business due to reimbursement at rates lower than the acquisition cost of the drug itself, which can lead to reduced patient choice and accessibility, both critical elements of a viable healthcare system that must be preserved.

  For example, DIR fees are often tied to quality metrics that are 1) inappropriate as applied to pharmacies; 2) unrelated to the quality of services provided; or 3) both inappropriate and irrelevant as a measure of a pharmacy's performance. For example, measures related to the generic dispensing rate may be inappropriate as applied to a specialty pharmacy that dispenses primarily single-source drugs. A pharmacy that does not "score" well on this measure could end up being unfairly judged as a suboptimal performer, then penalized with an unduly high DIR fee. The drastically lowered revenue experienced by such pharmacies, resulting from a PBM's "claw back" of DIR fees, can threaten the survival of many pharmacies, without contributing to the quality of care provided. The exit of these pharmacies from the PBM networks, in turn, can negatively impact access for many patients as willing providers are eliminated from the networks.

  Pharmacies are also adversely impacted because DIR fees may not be calculated by the PBM until the end of some specified period, e.g., quarterly. For this reason, pharmacies cannot determine their actual reimbursement rate, minus the DIR fees, until well after they have dispensed the medication. The resultant inability to correctly anticipate revenue is a challenge for these

pharmacies and may ultimately create a business reality that reduces the number of specialty pharmacies available to patients. Given the level of patient counseling, interaction, and monitoring that is necessary to ensure a patient appropriately takes and adheres to a medication to avoid serious adverse events, reducing the number of pharmacies would ultimately place patients at serious risk for harm.

Furthermore, since concerns with DIR fees have been raised in recent years, specialty pharmacies are now seeing other "unique" contracting strategies used by PBMs that incorporate elements such as administrative fees, network rebates, performance payments, network variable rates, and other fees. The common theme regardless of how these fees are identified is that they continue to reimburse specialty pharmacies below the acquisition cost of the drug, thereby placing specialty pharmacies in financial constraint and at risk of being forced to close and no longer be able to provide patient care.

While Premier is pleased that CMS is considering reform to address this unfair behavior and foster greater transparency in the CY 2023 Medicare Advantage and Part D Final Rule (CMS-4192-F), Premier believes that CMS' current proposal to address pharmacy price concessions does not go far enough to address the impact to pharmacies and patient access. Therefore, further investigation by the FTC into the impact of DIR fees is warranted.

- 340B Drug Discount Program – Another PBM tactic has targeted the 340B drug discount program and attempted to reduce the scope and benefits of the program. PBMs have created terms and policies that discriminate against 340B hospitals by paying them less than non-340B hospitals for certain outpatient drugs in order to protect their rebate revenue from drug manufacturers. This practice, known as "discriminatory 340B pricing," threatens the viability of hospitals by establishing barriers for pharmacies that 340B hospitals contract with to participate in their networks, disallowing PBM members from using 340B pharmacies, and even wholly excluding certain hospital-based pharmacies from their networks. While some states have explicitly prohibited 340B discriminatory pricing by PBMs, this practice requires federal investigation by the FTC.

  PBMs are also imposing significant burden on 340B covered entities by requiring the use of certain claim modifiers to include 340B eligibility at the point of adjudication. In addition, PBMs are asking hospitals to routinely audit claims and respond within a very short window, sometimes days, to demonstrate 340B eligibility.

- Spread Pricing – Spread pricing occurs when health plans contract with PBMs to manage their prescription drug benefits, and PBMs keep a portion of the amount paid to them by the health plans for prescription drugs instead of passing the full payments on to pharmacies. Thus, there is a spread between the amount that the health plan pays the PBM and the amount that the PBM reimburses the pharmacy for a beneficiary's prescription. If spread pricing is not appropriately monitored and accounted for, a PBM can profit from charging health plans an excess amount above the amount paid to the pharmacy dispensing a drug, which increases Medicaid costs for taxpayers.

III. Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on FTC-2022-0015-0001. Premier looks forward to working with the FTC and other stakeholders to create

transparency standards for PBMs and deliver sustainable market-based solutions to address the rising cost of pharmaceuticals and healthcare.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Vice President of Advocacy, at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Blair Childs
Senior Vice President of Public Affairs
Premier Inc.

Attachment A

GPOs, PBMs, and WDs differ in their statutory and regulatory authority, business models, and transparency requirements

	Group Purchasing Organization (GPO)	Pharmacy Benefit Manager (PBM)	Wholesale Distributor (WD)
Statutory and Regulatory Authority	• **Safe Harbor**: There is both a statutory exception and a regulatory safe harbor under the anti-kickback statute (AKS) for vendor payments to GPOs (42 CFR 1001.952(j)) that specifies reporting requirements.	• **Safe Harbor**: There is no statutory safe harbor specific to manufacturer payments to PBMs, although the broad discount safe harbor (42 CFR 1001.952(h)) is applicable if a PBM receives discounts or rebates for its own purchases or as agent for a plan.	• **Safe Harbor:** There is no statutory safe harbor specific to manufacturer payments to WDs, although the broad discount safe harbor (42 CFR 1001.952(h)) generally provides compliance protection to the purchases and sales conducted by WDs.
Business Models	• **Purpose:** GPOs exist to pool the purchasing power of hospitals, health systems and other providers, using scale and streamlined processes to establish purchasing contracts on behalf of their members, create efficiency in the supply chain process, and drive price savings from suppliers. Most GPOs are owned by providers. • **Contracting**: Manufacturers contract with GPOs to provide medications and health care supplies at a negotiated price. GPO members then determine which GPO contracts they would like to use to purchase products at the negotiated price from the manufacturer. • **Fees**: The GPO safe harbor protects GPO administrative fees of up to 3% of the purchase price, with additional transparency requirements for administrative fees in excess of 3%. According to the GAO, GPO administrative fees average 2%. Admin fees are calculated on the net negotiated contract price. • **Research**: Independent research [i] [ii]has affirmed the GPO business model as an overall cost savings model. The courts have also concluded that the GPO business model does not violate anti-trust laws.	• **Purpose:** PBMs exist to administer prescription drug plans on behalf of health plans, employer groups, and others. PBMs perform administrative functions such as claims processing, appeals and grievances, and managing the drug formulary. PBMs also negotiate drug prices and rebates with manufacturers. • **Contracting**: Health plans, employer groups, and others contract with PBMs to administer the pharmacy benefit. PBMs in turn contract with a pharmacy network where patients may access their medications. • **Fees**: PBMs collect administrative fees from customers and rebates from drug manufacturers. The rebates are in some cases based on the list price of the drug set by the manufacturer. The amount of collected rebates that are passed through to a PBM's customer are generally determined contractually, although PBMs must pass through 100% of rebates to Medicare Part D plan sponsors. • **Research**: There is little independent research assessing the value of PBMs. Some studies have found that PBMs have an adverse impact on the overall costs and prices of pharmaceuticals, and encourage an overly-complicated pricing structure.	• **Purpose:** WDs exist to perform logistics functions in the drug supply chain process as the primary system for moving drug inventory from the point of manufacture to providers. WDs primary supply chain function is highly regulated by the Food & Drug Administration, state pharmacy licensing entities, and Drug Enforcement Administration. • **Contracting:** WDs have a variety of contractual relationships with manufacturers and other stakeholders in the supply chain such as PBMs, managed care organizations, pharmacies, hospitals, long term care facilities, and outpatient clinics. WDs contract with manufacturers and other subsidiary distributors to deliver drugs. • **Fees:** WDs fees are based on negotiated cash discount rates that are a percent of the wholesale acquisition price set by the manufacturer, e.g. the list price or WAC. Through distribution service agreements, brand name manufacturers compensate wholesalers for having achieved negotiated performance goals; these fees are calculated as a percentage of a drug's list price.[iii] WDs have, more recently, developed additional administrative fee-based lines of service, e.g., "hub" services, supply chain data, and specialty distribution. • **Research:** There is little independent research assessing the value of WDs.
Transparency Requirements	• **Reporting**: In order to meet the safe harbor, GPOs are required to report all fees to provider members annually and upon request to HHS. • **Transparency**: Each GPO that participates in the Healthcare Group Purchasing Initiative (HGPII) maintains a Code of Conduct and voluntarily participates in the HGPII Ethics and Transparency Initiative. GPO business practices are publicly reported on the HPGII website.	• **Reporting:** PBMs providing services to Part D plans are required to report and pass on to the plan sponsor the aggregate amount of rebates and discounts received, but there is no public reporting of the specific amount of individual rebates, fees, and other reimbursements. • **Transparency**: PBM business models are not available publicly.	• **Reporting:** Absent (1) a specific AKS regulatory safe harbor and (2) a direct insurance claims submission function, WDs do not have formal administrative fee reporting obligations. The structure of the terms of their supply agreements and service arrangements are, however, subject to AKS compliance criteria, e.g., 42 U.S.C. § 1320a-7b(b)(3)(A). • **Transparency:** WD business models are not available publicly
Industry Financials	• **Revenue:** The GPO industry has grown 3.1% over the last 5 years to reach a total revenue of $5 billion in 2018. This number, however, does not include financial distributions made to member providers. This substantially reduces GPO operating revenues by an estimated 50% or more. [iv]	• **Revenue:** The PBM industry has grown 9.6% over the last 5 years to reach a total revenue of $453 billion in 2018.[v]	• **Revenue**: The WD industry has grown 4.7% over the 5 years to reach a total revenue of $990 billion in 2018. [vi]

[i] Burns, L. R. and J. A. Lee. (2008). Hospital Purchasing Alliances: Utilization, Services, and Performance. Health Care Manage Rev 33(3), 203-215

[ii] Hu Q, Shwarz L. (2011). The Impact of Group Purchasing Organizations on Healthcare-Product Supply Chains. Purdue University.

[iii] How Wholesalers Proft From Brand-Name Drug Inflation (But Not Perhaps As Much as You Think" October 22, 2015

[iv] Ibis World. (2019). Group Purchasing Organizations Industry in the US

[v] Ibis World. (2018). Pharmaceutical Benefit Management Industry in the US

[vi] Ibis World. (2018). Drug, Cosmetic & Toiletry Wholesaling Industry in the US