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ALERT

# Finding Calm During the PBM Storm: What Health Plans Can Do As FTC Litigation Intensifies

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Tensions between the Federal Trade Commission (FTC) and pharmacy benefit managers (PBMs) continue to mount, bringing PBM practices and calls for reform back into the spotlight. On September 17, 2024, one of the largest PBMs, Express Scripts, Inc. (ESI), sued the FTC for its descriptions of PBMs and their industry practices in a July 2024 Interim Staff Report (Report). The Report asserts, among other claims, that PBMs influence drug prices and access to medications via market consolidation and integration with other PBMs, health insurers, and/or providers, often leading to higher costs for consumers (plan sponsors and members). The Report calls for greater transparency within the PBM industry and could inform potential legislative/regulatory reform efforts.

ESI claims that the Report's findings are misleading, are unsupported by the empirical data provided by ESI to the FTC, and reflect an FTC bias against PBMs. The ESI complaint specifically alleges violations of state defamation laws as well as denial of due process under the Constitution and the Administrative Procedure Act. ESI has demanded retraction of the Report and recusal of FTC Chair Linda Khan.

On the heels of the ESI lawsuit, the FTC recently moved forward with its own PBM-related action. On September 20, 2024, the FTC filed an administrative complaint against the three of the largest PBMs – ESI (and their affiliated group purchasing organizations (GPOs)), Caremark Rx, and OptumRx – for engaging in anticompetitive behavior and unfair rebating practices that negatively affected consumers and increased drug prices. Responses to the FTC's complaint by one or all of the targeted PBMs are likely to be filed in

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## Practice Areas

Health Care

Pharmacy Benefit Manager (PBM) Contracting

the coming weeks.

Given this highly litigious environment encircling the PBM industry – and the allegations and defenses being raised – it is easy to assume that the status quo should be maintained until these issues are resolved. But is that the best and most strategic approach available now to a health plan? We think there are other options to consider, which we outline below.

## What Actions Should Health Plans Consider/Undertake During this Season of Discontent?

As the FTC and PBMs continue to battle over the positions outlined in the Report, anyone steeped in the world of health plan-PBM contracting will acknowledge that the Report indeed does reflect concerns that are consistently raised by health plans in their dealings with PBMs. Thus, no matter whether ESI ultimately proves that the FTC's interim findings are unsupported by data, or the FTC proves that certain PBMs engage in anticompetitive practices, health plans must continue to contract with PBMs and address those concerns causing unease (whether such concerns reflect unsupported gossip or provable allegations). Accordingly, identified below are certain concerns raised in the Report that, as a health plan, you should consider addressing now in your PBM contracts:

### Horizontal and Vertical Integration

One of the primary issues addressed in the Report is how the six largest PBMs are gaining market power. The Report claims the PBMs are increasing their existing market share by merging/acquiring one another (horizontal consolidation) while simultaneously expanding their market power by owning/operating downstream players within the drug supply chain, including mail order and specialty pharmacies (vertical integration). The Report maintains that as a result of controlling market share both horizontally and vertically, PBMs are incentivized to utilize their own affiliated businesses to wield power over prescription drug access and affordability without challenge due to minimal competitors in the market space. In fact, in the Report the FTC contends that due to this increased market power, the six largest PBMs process nearly 90% of all drug claims in the U.S.

However, despite the continued consolidation and vertical integration of PBMs, health plans may minimize any adverse impact by contractually limiting the rights and responsibilities of PBM-affiliated organizations. For example, PBMs often will seek to include their affiliates as parties to the PBM contract so that their affiliated businesses maintain the same rights and controls as the PBM under the contract. Health plans, however, may choose to limit the rights of their PBM's affiliates under their PBM contracts by treating those entities as subcontractors (rather than as a contracting party) that perform only certain pharmacy program services under the agreement (all subject to the health plan's expressed approval), and that have access to/the right to use only certain pharmacy program data. In other words, via contract, a health plan may carve out specific clauses that identify and limit PBM affiliate relationships. Health plans are encouraged to consult their counsel on how to best analyze and address the role of PBM affiliates and the contractual provisions necessary to support/protect their pharmacy program.

### Steering Through Expanding Specialty Drug List

The Report also addresses the PBMs' alleged classification/re-classification of certain drugs to permit those drugs to be dispensed by an affiliated company (e.g., the classification of a drug as a specialty drug to be dispensed by the PBM's specialty pharmacy). According to the Report, PBMs and their health plans have relatively broad discretion to make specialty classification decisions for prescription drugs given the lack of an industry standard or regulatory definition for a specialty drug. The Report explains that once a drug is added to a PBM's specialty drug list, this may trigger exclusivity provisions in contracts requiring the use of the PBM's affiliated specialty pharmacy when dispensing a member's specialty drugs.

To protect against PBMs steering prescription drugs toward their affiliated pharmacies via formulary changes, health plans may maintain leverage over their formularies by exercising final approval rights over the content, form, format, and/or frequency of their formularies and formulary changes (including inclusions or exclusions or reclassifications of preferred and non-preferred drugs) under their PBM contracts. Health plans are encouraged to consult their counsel on specific contractual provisions that will help the health plan maintain final and sole authority over the composition of its formularies.

### Network Pharmacies

The Report further addresses PBM networks and the PBMs' control over independent pharmacies. Due to the horizontal consolidation of PBMs, the Report claims independent pharmacies often are constrained to enter into non-negotiable contracts with the leading PBMs to serve patients/members. As a result, the Report indicates that PBMs have both enormous leverage over unaffiliated, independent pharmacies and the ability and incentive to act in ways that are detrimental to those pharmacies with limited recourse over unfavorable terms offered by the PBM.

Health plans can maintain leverage over PBM network pharmacies by requiring that certain contract requirements be incorporated into the PBM's network contracts for health plans' membership. As described in our previous alert, health plans rely upon the PBM to build pharmacy networks. As a result, health plans typically do not have direct contracts with their network pharmacies (whether such pharmacies are affiliated with the PBM or non-affiliated/independent). Therefore, health plans should consider requiring (by way of contract) that their PBM include in its network pharmacy contracts terms that are advantageous to the health plan and its members. Health plans are encouraged to consult their counsel on those pharmacy network contract provisions that are necessary to equalize the playing field between affiliated and non-affiliated/independent pharmacies.

### Group Purchasing Organizations (GPOs)

The Report also includes a brief discussion on the GPOs established by the big three PBMs, which GPOs are otherwise referred to as rebate aggregators. There is little dispute that GPOs were created by PBMs to negotiate contracts, including rebates, with drug manufacturers. However, the Report maintains that a consequence of these organizationally affiliated rebate aggregators is that these structures enable PBMs to retain large amounts of rebate revenue rather than passing the revenue to their health plans or their

members.

In May and June 2023, the FTC issued supplemental 6(b) Orders to the big three PBMs' GPOs to learn more about their practices, which production is anticipated to be completed in 2025. Regardless of the validity of the FTC's claims concerning the purpose/consequences of PBM-affiliated GPOs and their practices, many health plans are seeking to receive (and may be obligated to provide to their ASO customers) 100% of the rebate value based on their book of business. Health plans should consult their counsel on those contractual provisions necessary to extract the greatest level of rebates available to that health plan given the health plan's utilization and positioning in the market, among other factors.

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While the Report highlights ongoing concerns around how PBMs operate in the marketplace, these issues are not new and have long been contemplated by health plans as they enter into and/or negotiate their PBM contracts. Health plans can and should be able to address by contract many of these concerns by working with experienced counsel in drafting and negotiating their PBM contracts. Wiley's PBM Contracting team of experienced attorneys and advisors is closely monitoring the FTC's investigation into PBMs and corresponding litigation and is available to assist with any questions.