MINTZ

Special Edition: FTC Interim Report

PBM

Policy and Legislative Update

July 2024

The Federal Trade Commission (FTC) Office of Policy Planning released an Interim Staff Report titled *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (the Interim Report) on July 9, 2024. The Interim Report reflects the FTC's work since it began its 6(b) study of Pharmacy Benefit Managers (PBMs) in June 2022. Our Health and Antitrust teams actively monitor federal and state regulatory and legislative developments in the PBM space, including those coming from the FTC. In this *Special Edition* of the *PBM Policy and Legislative Update*, we paired up with our Antitrust colleagues to highlight the FTC's recent activity in investigating the potential competitive consequences from conduct in the PBM industry, including Commissioner Melissa Holyoak's dissenting statement regarding the Interim Report, and reports of a forthcoming action against the major three PBMs related to insulin rebate practices. The Mintz Health and Antitrust practices will continue to monitor enforcement actions and policy advocacy from the FTC in this space.

Current FTC Chair Lina Khan has been active in advocating against certain PBM practices since her confirmation in June 2021. The Interim Report released on Tuesday, July 9, 2024, is a preliminary report on an inquiry of the PBM industry and market that was launched by the FTC in June 2022 pursuant to the Commission's authority under Section 6(b) of the Federal Trade Commission Act to investigate markets. FTC Commissioner Holyoak notes in her dissent that the Interim Report fails to meet the rigorous standard of excellence requiring evidence-based, objective, and economically sound conclusions that is historically associated with FTC 6(b) studies.

Key Takeaways from the Interim Report

Concentration and Vertical Integration. The Interim Report raises concerns that PBM consolidation and resulting market concentration coupled with vertical integration within healthcare conglomerates has resulted in competitive concerns over access to and affordability of medications. The FTC is concerned that vertical integration has resulted in PBMs having the ability and incentive to preference their own affiliated entities over rival entities, as well as lessening competition in various parts of the pharmaceutical supply chain.

Steering. The Interim Report discusses the various mechanisms PBMs employ to steer patients and prescriptions, particularly specialty prescriptions, to PBM-affiliated pharmacies. In particular, the FTC focuses on PBMs' ability to steer prescriptions by classifying drugs as "specialty drugs." The FTC states that PBMs may also "have a particularly strong incentive to capture specialty prescriptions at their affiliated pharmacies, given their high prices and margins" and notes that some PBM contracts with payers contain exclusivity provisions requiring the use of only the PBM-affiliated specialty pharmacy for specialty drugs. A trend analysis conducted by FTC staff for years 2017-2021 showed an increase in the overall number of drugs on the specialty drug lists for each of the top PBMs from whom the FTC was able to obtain data. The FTC attributes this not only to the increase in the number of drugs available on the market, but also to PBMs' broad discretion to determine what constitutes a "specialty drug".

Reimbursement Rates and Dispensing Revenue. The Interim Report claims that insurers and health plans reportedly pay higher reimbursement rates at PBM-affiliated pharmacies for specialty drugs and specialty generics compared with prices paid for such drugs at unaffiliated pharmacies. The Interim Report includes two case studies meant to illustrate this principle, finding that health plans using PBMs to deliver pharmacy benefits reimburse their PBM-affiliated pharmacies for the two case study drugs at higher rates than the National Average Drug Acquisition Cost. The FTC asserts that the high reimbursement rates paid to PBM-affiliated pharmacies for these drugs translate to substantial revenue gains for PBM-affiliated pharmacies and may lead to high out-of-pocket costs for patients and, ultimately, decreased drug utilization.

Bargaining Leverage. The Interim Report asserts that pharmacies have little bargaining power in PBM contract negotiations. The FTC further asserts that, given the number of lives covered and dispensing volume controlled by the top six PBMs, independent, unaffiliated pharmacies are effectively coerced into non-negotiable, lopsided contracts with PBMs or risk losing business. Additionally, the Interim Report suggests that PBMs use their market power to put downward pressure on reimbursement rates for unaffiliated pharmacies, using complex reimbursement arrangements not easily understood by most pharmacies and sometimes setting rates below independent pharmacies' costs.

Rebates and Exclusion of Generics. While the Interim Report primarily focuses on PBM-pharmacist relationships, it briefly touches on the FTC's concerns regarding PBMs' exclusionary rebate arrangements with manufacturers. The FTC states that its initial review of certain PBM-manufacturer contracts reveals rebate structures that may "impede and impair competition and patient access to affordable medications" and contract provisions that premise high rebates on the exclusion of certain generics and biosimilars. Additionally, the FTC expressed concern over the recent emergence of, and PBMs' use of, rebate aggregators and issued supplements to the original 6(b) orders to the top three PBMs' rebate aggregators to obtain additional documents and information to learn more about their operations. The FTC expects the data production from these supplemental orders to conclude in 2025.

Commissioner Holyoak Dissent. Newly appointed Commissioner Melissa Holyoak issued a dissenting statement contending that the Interim Report fails to meet the economic rigor expected of FTC 6(b) studies, noting that the Interim Report does not examine how PBM practices affect consumer prices or provide empirical evidence supporting its claims regarding the market power of PBMs or the state of competition in the PBM industry. Commissioner Holyoak further criticized the Interim Report for its failure to address the findings of the **2005 report on the PBM industry**, where the FTC concluded that PBMs, including vertically-owned PBMs, generated cost savings for consumers. Commissioner Holyoak believes the Interim Report's two case examples are not a substitute for rigorous economic analysis and that the Interim Report fails to provide a credible basis for future Commission action against PBMs.

It is ONLY an Interim Report. The FTC notes that the study is still ongoing and that the Interim Report focuses on the impact of consolidation, vertical integration, and changing market dynamics on the "operation and vitality of the nation's pharmacies." As noted above, the FTC maintains that some of the PBM respondents have not yet fully complied with the study order information requests, and the failure to timely produce documents and data has "hindered the ability of the Commission to perform its statutory mission." We expect further reporting ahead.

Other Recent Activity in the PBM Space

- **July 2024 – WSJ Reports FTC is Preparing to File Complaint in Insulin Matter.** The day immediately following the release of the Interim Report, the Wall Street Journal (WSJ) reported that the FTC plans to file a lawsuit against the three largest PBMs over tactics related to negotiating insulin rebates. The WSJ article also claims that the FTC is investigating the role that insulin manufacturers play in those negotiations.

- **July 23, 2024 – PBM Executives to Testify Before Congress.** Executives from the three largest pharmacy benefit managers are scheduled to testify before the House Oversight Committee on July 23.

Timeline of FTC Activity in the PBM Space

- **June 2022 – FTC Issues 6(b) Study Orders to Six Largest PBMs.** The Commission announced its inquiry into the effect of PBM practices on pharmacies, payers, doctors, and patients. The inquiry was focused on several PBM practices, including fees and clawbacks charged to unaffiliated pharmacies, methods to steer patients to PBM-owned pharmacies, potentially unfair audits of independent pharmacies, complicated and opaque methods to determine pharmacy reimbursement, the prevalence of prior authorizations and other administrative restrictions, the use of specialty drug lists and specialty drug policies, and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients. Chair Khan said in a statement accompanying the study orders: "While unknown to much of the American public, PBMs are powerful intermediaries at the center of the U.S. prescription drug system.... Given that PBMs' practices can have life-and-death consequences for Americans, the FTC has a moral imperative to act with urgency on this issue."

- **May 2023 – FTC Deepens PBM Inquiry.** The FTC issued additional 6(b) orders to two group purchasing organizations (GPOs) engaged in the practice of negotiating rebates with drug manufacturers on behalf of PBMs, noting that information received from the GPOs will shed further light on the competitive implications of PBM practices.

- **May 2023 – FTC Files Merger Litigation on Bundling Theory.** The FTC filed and then settled a lawsuit to block Amgen from acquiring another pharmaceutical manufacturer, Horizon Therapeutics (Horizon). In the September 2023 settlement Amgen agreed as a condition of its acquisition of Horizon (i) not to pursue exclusionary rebate practices with respect to the acquired Horizon drugs, (ii) to submit all contracts signed with insurers related to the acquired Horizon drugs to an FTC appointed monitor, and (iii) to seek approval from the FTC prior to purchasing drugs that are competitive with the acquired Horizon drugs. The FTC's complaint alleged that cross-market rebating and bundling, which involves conditioning rebates on one product in exchange for formulary placements for other unrelated

products, can block smaller rivals from being able to compete on the merits and forecloses competition. The FTC stated that it intends to keep exclusionary rebates on its radar.

- **July 2023 – FTC Warns Public Not to Rely on Prior PBM-Related Advocacy Statements and Reports.** The majority at the FTC voted to issue a statement cautioning industry participants against relying on previous PBM guidance issued by the FTC, including nine advocacy letters, a 2004 joint report with the United States Department of Justice Antitrust Division, and a 2005 FTC study.

- **January 2024 – Senator Grassley Writes to FTC Regarding the 6(b) Study.** Senator Chuck Grassley, along with a bipartisan coalition of U.S. Senators, writes a letter to Chair Khan, urging the FTC to complete its 6(b) study of PBMs in a timely manner. The letter advocated for the FTC to release a public progress report.

- **February 2024 – FTC Responds to Senator Grassley.** Chair Khan responds to Senator Grassley and describes the challenges the FTC has faced in obtaining information from the PBMs and GPOs. In the letter, Chair Khan responds that none of the PBMs have turned over sufficient documents and data to be in full compliance with the investigation's compulsory orders, making it difficult for the FTC's inquiry to proceed. Expressing hope to receive the information soon, Chair Khan writes of the FTC's readiness to take the PBMs and GPOs to court to compel compliance.

- **July 2024 – FTC Issues Interim Report on Prescription Drug Middlemen.** Chair Khan noted in a statement that there is "enormous urgency" in understanding PBMs' practices and that the FTC Staff continues to push the respondent PBMs to produce the data necessary to do a full analysis of the effect of PBM practices on prices. In response to Commissioner Holyoak's dissent that the Interim Report is void of rigorous economic analysis, Chair Khan responds that the Interim Report "lays out an initial economic analysis, including a discussion of how exclusionary rebates may be having negative spillover effects on competition in drug markets, impeding generic entry."

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Our team possesses unparalleled expertise within the intricate world of Pharmacy Benefit Management (PBM). Navigating the maze of federal and state laws and regulations can be daunting for PBMs and the entities with which PBMs do business. That's where we come in. With an in-depth understanding of the PBM industry, legal frameworks, and policy trends, we offer insightful and strategic guidance to help clients meet their business objectives.

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