FTC Publishes Long-Awaited Interim Report on PBMs

What Happened

On July 9, 2024, the Federal Trade Commission (FTC) released a long-awaited interim staff report on Pharmacy Benefit Managers (PBM) and their influence over patient affordability and access to medicine. The interim report comes as part of an ongoing FTC investigation of PBM practices launched in 2022. FTC chair Lina Kahn cited "enormous urgency in understanding PBMs' practices" as the reasoning behind the release of this interim report but notes that the FTC's investigation is not yet complete as the PBM's subject to the investigation have not cooperated with FTC's demands for information. The release of the interim report could fuel the current legislative initiatives on PBM reform and hopefully will further incentivize Congress to act this year.

Who It Impacts

While the interim report addresses concerns about PBMs' relationship with drug manufacturers (i.e., negotiating brand manufacturer rebates to limit generic and biosimilar use), the report focuses more on how PBMs wield power over pharmacies. The release of the interim report is powerful and marks a shift in the FTC's view of PBMs, but it notably does *not* call for enforcement action such as putting limits on PBM business practices or breaking up PBMs from insurers and pharmacies. The FTC is not ruling out potential action(s), but rather issued this report as providing the public with "key insights supported by the documents and data obtained to date."

What Does It Say

FTC's findings describe much of what we know to be true about PBM market power and the significant influence they have over what medications patients have access to and how much they pay for them in all markets.

Highlights of the FTC's findings include:

- **Concentration and Vertical Integration:** FTC found the market for PBM services to be "highly concentrated," with the largest PBMs also vertically integrated with the largest health insurers and specialty and retail pharmacies. Today, the top three PBMs-CVS Caremark, Express Scripts, and OptumRx manage 79% of prescription drug claims for approximately 270 million people. With the next three largest PBMs-Humana Pharmacy Solutions, MedImpact, and Prime—the six largest PBMs now manage 94 % of prescription drug claims in the United States.

- **Significant Power and Influence:** As a result of consolidation and vertical integration, the leading PBMs exercise significant power over patients' ability to access and afford their prescription drugs. The largest PBMs often exercise significant control over what drugs are available and at what price, and which pharmacies patients can use to access their prescribed medications. PBMs oversee critical decisions about access to and

affordability of life-saving medications, without transparency or accountability to the public.

- **Self-Preferencing**: Vertically integrated PBMs appear to have the ability and incentive to prefer their own affiliated businesses, creating conflicts of interest that can disadvantage unaffiliated pharmacies and increase drug costs. PBMs also may be steering patients to their affiliated pharmacies and away from smaller, independent pharmacies. These practices have allowed pharmacies affiliated with the three largest PBMs to retain high levels of dispensing revenue in excess of their estimated drug acquisition costs, including nearly $1.6 billion in excess revenue on just two cancer drugs (Zytiga and Gleevec) in under three years.

- **Unfair Contract Terms:** Evidence suggests that increased concentration gives PBMs leverage to enter contractual relationships that disadvantage smaller, unaffiliated pharmacies.

- **Limiting Access to Low-Cost Competitors:** PBMs and brand drug manufacturers negotiate prescription drug rebates some of which are expressly conditioned on limiting access to potentially lower-cost generic and biosimilar competitors.

- **PBM and Drug Manufacturer Rebating Practices:** FTC identified areas for ongoing focus and specifically notes PBM and drug manufacturer rebating practices as an area that "urgently warrant further scrutiny and regulation." Based on the findings published in the interim report, FTC is most interested in how PBMs use exclusionary rebates to determine formularies and ultimately patient access to medicine. FTC cites specific rebating practices they are most concerned with, such as:
    - Preferring highly rebated drugs on formulary tiers, demanding rebates that would require "brand step" requirements (i.e.: "fail first" step therapy).
    - Demanding rebates that impose prior authorization requirements.
    - Conducting "other methods" to enhance the financial gains from rebate contracts, including the use of rules to indicate when the pharmacy's substitution of a particular product is not permitted (known as "dispense as written" or "DAW").
    - Excluding generics and/or biosimilars from formularies.

Next Steps

The FTC will continue their work, as the report notes that several of the PBMs that were issued orders have not completed their required submissions, which has hindered the Commission's ability to complete its work. We expect there to be a final report released, but it's unclear when that will occur.