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*Special Edition: FTC 2nd Interim Report*

# PBM

## Policy and Legislative Update

**January 2025**

The Federal Trade Commission (FTC) Office of Policy Planning released a second "Interim Staff Report" as part of its inquiry into PBMs on January 14, 2025, titled *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* (the "Second Report")—quieting rumors that the "final" PBM report would not be released prior to the end of Chair Lina Khan's tenure at the helm of the agency. The Second Report reflects additional work the FTC completed since it released the July 2024 Interim Staff Report (the "First Report"), which we covered here. Most notably, the Second Report includes the empirical analysis the First Report was criticized for lacking.

The Second Report focuses on reimbursement of specialty drugs and is meant to present "a more comprehensive analysis of how the PBM respondents reimburse specialty generic drugs at their affiliated pharmacies and unaffiliated pharmacies." The FTC concludes that specialty generic drugs "represented a growing profit center for the Big 3 PBMs and their affiliated pharmacies during [the] study period from 2017 through part of 2022" and the "Big 3 PBMs marked up numerous specialty generic drugs by hundreds and thousands of percent, with the majority of the most highly marked-up drugs dispensed by the PBMs' own affiliated pharmacies."

In this Second Report, the FTC further finds that the Big 3 PBMs' affiliated pharmacies generated significant and growing levels of revenue in excess of estimated acquisition cost on the most highly marked up specialty generic drugs during the study period; while at the same time, the Big 3 PBMs appeared to take in significant income from spread pricing, as the amounts paid by plans and patients increased. The Second Report concludes by calling for further scrutiny of specialty generic drug pricing and steering practices, as well as potential legislative reforms by Congress and the states—noting that consumers "are paying the Big 3 PBMs and their affiliated pharmacies very significant markups over the acquisition costs for critical medications."

The FTC press release accompanying the Second Report makes clear that the 6(b) study is ongoing and that the FTC may provide additional updates as it continues to receive and review information submitted in response to its inquiries. It is possible there could be additional interim reports before the FTC issues its final analysis. Though the FTC will soon have a Republican chair appointed and President-elect Trump is set to nominate a third Republican commissioner to the FTC, the vote to issue the Second Report was unanimous. As readers of this *PBM Policy and Legislative Update,* you know well that scrutiny of PBM practices is a bipartisan issue. However, as it relates to the FTC inquiry, it remains to be seen whether the new Republican leadership at the FTC will take the same expansive view of Section 5 of the FTC Act.

As we noted in our *Fall 2024 PBM Policy and Legislative Update*, PBMs are challenging FTC actions, and we similarly expect the Big 3 to respond to the Second Report. ESI's defamation suit against the FTC challenging the First Report is ongoing as is the Big 3's request for an injunction to halt proceedings in the FTC's in-house case against the Big 3 regarding insulin rebating practices. We also note that the Big 3 PBMs have commissioned their own reports to respond to the FTC's Interim Staff Reports. We plan to provide an update on this activity in our *Winter 2025 PBM Policy and Legislative Update*.

# Second Report Key Findings

- **Markups for Specialty Generic Drugs Dispensed at PBM-Affiliated Pharmacies.** In addition to the two specialty generic cancer drugs analyzed in the First Report, the Second Report evaluates all specialty generic drugs dispensed during 2017-2022 for members of commercial health plans and Medicare Part D prescription drug plans for which the FTC has relevant data. The FTC finds that the Big 3 PBMs marked up numerous specialty generic drugs dispensed at affiliated pharmacies by "hundreds" of percent and marked up oncology, multiple sclerosis ("MS"), and pulmonary hypertension drugs by "thousands" of percent, up to a staggering 7,736% in 2022 for certain pulmonary hypertension medications. According to the FTC, some market participants were unaware that many of the specialty generic drugs would be subject to such high markups. FTC staff also reviewed various emails produced by PBM respondents in which plan sponsors and consultants raised concerns after learning of the high markups.

- **Dispensing Patterns.** According to the Second Report, despite PBM-affiliated pharmacies having dispensed 45% of commercial specialty generic 30-day equivalent prescriptions overall, 72% of prescriptions for drugs marked up more than $1,000 were dispensed by PBM-affiliated pharmacies, suggesting that PBMs may be steering highly profitable prescriptions to their own affiliated pharmacies and away from unaffiliated pharmacies. The FTC reports that these results corroborate documents produced by the PBMs that discussed different tactics and strategies to steer patients to affiliated pharmacies and to block the dispensing of "low/no margin drugs" at their affiliated pharmacies. Unlike the commercial claims, PBM-affiliated pharmacies dispensed fewer 30-day equivalent prescriptions than unaffiliated pharmacies on Medicare Part D claims, which the FTC asserts suggests that PBMs have less influence over patient pharmacy choices in Part D.

- **Revenue in Excess of NADAC.** The Second Report notes that the Big 3 PBMs generated over $7.3 billion of dispensing revenue in excess of NADAC on the specialty generic drugs analyzed as part of the study, with oncology, MS, transplant, HIV, and pulmonary hypertension drugs accounting for more than 94% of the $7.3 billion. The Second Report explains that revenue in excess of NADAC increased at a compound annual rate of over 42% from 2017 to 2021, and because the Big 3 PBMs' acquisition costs tend to be lower than NADAC, the revenue calculations listed in the Second Report are likely to be underestimated. The Second Report further points out that 19% of the revenue in excess of NADAC was generated from Medicare Part D claims, reinforcing its assertion in the First Report that such PBM practices could lead to an increase in government and beneficiary spending.

- **PBMs Generated >$1 Billion in Income from Spread Pricing.** According to the Second Report, the Big 3 PBMs generated combined spread pricing income of approximately $1.4 billion between 2017 and 2021 solely from the 51 specialty generic drugs reviewed by the FTC, although the FTC admits that it made certain assumptions based on limited information.

- **Significant Increase in Share of Operating Income.** The Second Report shows that the operating income related to dispensation of the analyzed specialty drugs from the Big 3 PBMs' affiliated pharmacies accounted for 12% of the aggregated operating income reported by their parent healthcare conglomerates' business segments that include their PBM and pharmacy businesses in 2021, up from less than eight percent just two years prior, while the top 10 specialty generic drugs accounted for 10.7% of the operating income.

- **Plan Expenditures and Patient Cost-Sharing Increased.** The FTC reports plan sponsor and patient payments both increased at compound annual growth rates of 21% for commercial claims and 14-15% for Medicare Part D claims.

The Second Report notes that the FTC staff is "continuing to engage with selected PBMs regarding potential deficiencies as they work toward full compliance." The FTC also notes that it is still collecting information from PBM-affiliated rebate aggregators. Neither of the two sitting Republican commissioners dissented from issuing the Second Report, which signals willingness to continue to release empirical 6(b) interim reports during the Trump Administration and through a Republican majority at the FTC. We will continue to monitor the FTC's activity and keep you apprised of any updates. In the meantime, don't hesitate to reach out to our team with any questions.

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