FTC Indicates PBM Law Enforcement & Market Rule

New Drug Law (IRA) Impacts Rebates & PBM Strategies Over Time

In late June, we identified four PBM catalysts: FTC rulemaking, transparency bill, rebate rule, insulin. The ongoing FTC investigation and recent public remarks from FTC chair Lina Khan indicate how far the agency may attempt to go in hitting PBMs if it finds wide-spread anticompetitive conduct. The newly-passed *Inflation Reduction Act* will also impact Rebates/PBMs over time (by category).

- **Two old enforcement authorities may be employed for PBMs**. Chair Lina Khan stated that the FTC is looking to apply two older enforcement authorities -- Section Five and the Robinson-Patman Act -- to address rebating practices. These are legal authorities the agency has not enforced in decades, but complaints of "unfair" contracts from PBMs may bring them back into play.
  - Section Five prohibits "unfair or deceptive acts or practices in or affecting commerce."
  - Robinson-Patman Act prevents large businesses from engaging in price discrimination against smaller entities**.**

- **Recall that the Federal Trade Commission (FTC) voted 5-0 in June to investigate PBM anticompetitive conduct** (FTC Public Meeting, led by Commissioner Lina Kahn). FTC's intent is to examine rebates and fees paid by drug manufacturers to pharmacy benefit managers (PBMs) and other intermediaries in exchange for disfavoring the lowest cost drug products. Since the start of the investigation, chair Lina Khan has repeatedly stated that the FTC intends to use every tool they have to investigate drug manufactures, pharmacy middlemen, and prices. Insulin is included.

- **The FTC is investigating the Big 6, with a Report likely early to mid 2023**: Caremark; Express Scripts, OptumRx, Humana, Prime Therapeutics, and MedImpact Healthcare Systems. We expect to see a report and a potential rule. FTC believes that PBMs are keeping too much of the money from rebates and therefore increasing drug prices. Companies had 90 days from the order to respond and we expect the investigation to take several more months. The agency is gathering information on practices including PBM control over formularies, pressure on independent pharmacies, and spread pricing. Consolidation is also expected to be addressed.

- **The FTC PBM investigation is more onerous potentially than the Pharma merger review/new standards** according to our antitrust expert on June 16. FTC is looking to reassess what defines antitrust as it addresses increasingly consolidated markets (not just healthcare). PBMs are a key example of the agency looking beyond efficiency when assessing anticompetitive practices. Additionally, the agency is in the process of revising its merger guidelines**.** The FTC likely will no longer be satisfied with overlap divestitures as remedies under new guidelines.

- ***The Inflation Reduction Act*** **(Rx Negotiation, Part D Restructuring) will surely impact Rebate strategies from manufacturers**. The non-partisan MedPAC looked into rebating at its October meeting. New commissioner Kenny Kan (formerly HUM) remarked that IRA is expected to mitigate some of the access issues that come from high rebate drugs. Commissioners want to learn more on variables that go beyond net pricing: consolidation, MA and standalone PDPs, transparency.

- **NEXT STEPS:** (1) FTC's PBM study is not expected to conclude until 4Q22, with a report 1H 2023. Following release, we may see potential rulemaking re PBMs and rebates. **(2)** While the FTC may be ramping up oversight with new rules, the courts still have the final say in deciding anti-

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competitive conduct. We have seen the DOJ/FTC lose merger litigation cases, including United Health/Change. Despite recent losses, we believe the FTC will continue to bring cases to push for Congressional action on consolidated industries like PBMs. **(3)** Overall, we predict that increasing FTC enforcement and implementation of IRA provisions (negotiations, inflationary rebates, co-pay caps) will impact PBM rebating, and plans may experience a decline in rebate revenues from formerly high-priced drugs. **(4)** The Senate INSULIN bill (negative for PBMs) may also reappear during the lame duck period and beyond, with passage unlikely at this time due to competing end of the year healthcare priorities.

Background

A recap of other legislations that impact PBMs are listed below. We do not envision passage in 2022.

INSULIN BILL

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- **Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act was released (updated) in June by the leaders of the Diabetes Senate caucus.** The bill has been updated from a prior version and is expected to cost the federal government $23 B over 10.

- **Plans and PBMs would no longer receive rebates for insulin & related products in commercial group/individual, ERISA, Medicare Part D, and MA prescription drug plans (starting in 2024).** The bill also prohibits plans from imposing prior authorization on insulin products. If passed, the bill is expected to negatively impact PBM margins (CVS, UNH, CI, ANTM, HUM).

- **Passage would be especially hurtful to smaller players. By eliminating rebates and capping enrollee co-pays, an increasing share of the cost burden will fall on the plans**. This is likely not an issue for the big 5 PBMs that are aligned with insurers & have healthy cash flows but smaller PBMs will feel an impact to their bottom-line.

- **Starting in 2023, the bill caps insulin co-pays at $35 or 25% of the list price per month, whichever is lower ~ Commercial group/individual, ERISA, Medicare Part D, and MA prescription drug plans.** Catastrophic health insurance plans will also be required to provide coverage of selected insulin products. But this is not a free-for-all coverage. Plans (CNC, MOH, UNH) will still be allowed to impose higher cost-sharing if insulin products are delivered by an out of network provider.

PBM TRANSPARENCY BILL

- **Senate Commerce Committee (Chair Cantwell, D-WA) advanced the PBM Transparency Act in a 19-9 vote in June.** This act would prevent practices and the dissemination of "false" information related to PBM services for prescription drugs.

- **Spread pricing would be banned.** PBMs (1) cannot charge a health plan or payer a different amount for prescription drugs' ingredient cost or dispensing fee than the amount the PBM reimburse a pharmacy for the prescription drug (2) cannot reduce reimbursement payment to a pharmacist for a prescription drugs ingredient cost or dispensing fee (3) cannot increase fees or lower reimbursement to a pharmacy in order to offset reimbursement changes.

- **Spread is still allowed/predominant in Medicaid & Commercial.** CMS has made spread pricing nearly impossible in Medicare Advantage (MA).

- **OUR TAKE:** There is no House version of this bill yet. This near-permanent ban on spread unlikely passes this year but inclusion in a larger bill is not impossible at the end of the year. It's very unlikely to pass stand-alone.

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