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# Pharmacy Benefit Managers in the Crosshairs of Enforcement and Reform

*PBM reforms are evolving quickly, with major PBMs and their stakeholders seeking to influence the state-level regulatory landscape through constitutional challenges.*

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Pharmacy benefit managers have been in the crosshairs of enforcement and reform efforts for several years. At the federal level, the Federal Trade Commission has obtained favorable settlements for the government, and Congress passed PBM reform in the Comprehensive Appropriations Act in February. Some states have also enacted their own legislation, which has become the latest battleground as PBMs level constitutional challenges to state efforts to regulate PBMs' limitations on where and how patients can fill prescriptions. The outcome of these challenges may dictate whether other states take similar action, and whether PBM influence on pharmacy selection continues to grow.

## Overview and Criticisms

PBMs are third-party administrators of prescription drug benefits for health insurance plans. Their services include claims processing; drug utilization reviews; formulary development; and contract negotiation between health plans, manufacturers, and pharmacies. Three PBMs dominate the U.S. market, and they are each tied to a health insurer: Express Scripts to Cigna; Caremark Rx to CVS Health (which also owns CVS Pharmacy); and OptumRx to UnitedHealth Group. This vertical integration of PBMs, pharmacies, and insurers is widely criticized.

Beginning in 2024, the FTC brought enforcement actions against these three PBMs, alleging that they artificially inflated the list price of insulin drugs through practices that prioritized high rebates from drug manufacturers. As a result, the FTC alleged, even when lower-priced insulin was available to vulnerable patients, PBMs excluded it from their formularies in favor of more expensive, highly rebated insulin products.

Other frequently critiqued PBM practices include the following:

- "Spread pricing," where a PBM reimburses the dispensing pharmacy less than the cost charged to an insurance plan's sponsor, and the PBM retains the "spread";
- Non-transparent contracts, including provisions limiting pharmacists' ability to reveal alternative cost-sharing information with customers;
- Limiting patients to affiliated pharmacies and/or mail-order-only pharmacies; and
- "White-bagging," which requires use of mail-order specialty pharmacies for pre-dispensed treatments for use only by a specific patient.

**PBM Reforms**

The FTC settled its enforcement actions against Express Scripts and Caremark, and stayed its case against Optum pending approval of a tentative settlement. The Express Scripts and Caremark settlement agreements require the PBMs to amend their rebate structures, including by eliminating formulary preferences for high-cost versions of a drug and allowing health plan sponsors to transition away from rebate guarantees and spread pricing. The Express Scripts and Caremark settlements also provide for annual reports to health plan sponsors on drug costs and pharmacy claim-level reporting, and require covered access for TrumpRx, with direct-to-consumer pricing and payments counting toward deductibles and out-of-pocket cost maximums. Any settlement with Optum is expected to contain similar provisions.

Congress enacted additional PBM reforms through the CAA this year, which include a requirement that any rebates or other discounts negotiated by the PBM be "fully passed through" to the insurance plan. This means PBMs may not retain any portion of savings obtained through rebates negotiated with drug manufacturers; all such savings must be provided to the insurance plan. Further, the CAA targets PBMs' practice of linking compensation to drug list prices and manufacturer rebates by prohibiting incentive compensation for PBMs in any form other than a "flat dollar amount" at "fair market value." The CAA also institutes reporting requirements for PBMs and requires Medicare plans to accept "any willing pharmacy" in network.

Meanwhile, state legislatures have attempted to fill gaps in federal PBM regulations. All 50 states have passed some legislation regulating PBMs, and some states have enacted legislation targeting PBM practices that the FTC's recent enforcement actions and CAA did not address—including PBM limitations on patients' choice of pharmacy. Most recently, PBMs have leveled constitutional challenges to such reforms in Iowa, Arkansas, and Tennessee.

In 2025, Iowa passed PBM reform legislation that, among other things, creates "any willing provider" standards for pharmacy network participation, restricts patient steering, and bans mail-only prescription benefits. A coalition of Iowa organizations that rely on employer-sponsored health plans governed by ERISA—many of whom use PBMs—moved in the Southern District of Iowa for a temporary restraining order preventing enforcement of the law, alleging it impermissibly regulates plans that are exclusively within federal jurisdiction under ERISA. The court granted the preliminary injunction as to the aforementioned parts of the Iowa law because they likely (1) are preempted by ERISA and (2) violate PBMs' First Amendment rights by restricting protected commercial speech. Iowa's appeal to the U.S. Court of Appeals for the Eighth Circuit remains pending.

Arkansas' PBM reform legislation has faced similar challenges by Caremark and Express Scripts. Caremark challenged the law's "Mail Order Provision," which prohibits mail-order-only prescription benefits, and "Network Adequacy Provision," which mandates that PBMs serving a health plan ensure that a high percentage of covered individuals live within a certain distance from a network pharmacy. The district court granted Caremark's motion to dismiss for failure to

state a claim as to the Mail Order Provision because Caremark does not actually require that prescriptions be filled only by mail (they can also be filled at CVS pharmacies), and on grounds that the Network Adequacy Provision and related "Geographic Coverage Requirements" are preempted by ERISA. In affirming, the Eighth Circuit held that the rule was preempted by ERISA because it interfered with plan administration uniformity and required PBMs to take on the burden of "tailoring substantive benefits to the particularities of multiple jurisdictions."

Express Scripts sought a preliminary injunction of a separate portion of the Arkansas law, which prevents PBMs from owning or operating pharmacies in Arkansas. The district court granted the motion on two bases. First, Arkansas's law likely violates the Commerce Clause by overtly discriminating against out-of-state companies where other means are available to advance interests of eliminating PBM tactics that put locally operated pharmacies out of business. Second, TRICARE—the federal health care program for service members and their families—likely preempts the law because Congress clearly intended TRICARE to contract with PBM-owned pharmacies, and the law impedes TRICARE's ability to accomplish its objectives of "uniformity" and "national" scope. Arkansas appealed to the Eighth Circuit.

Tennessee's state legislature passed the Fair RX Act in May, which, like the Arkansas statute, prohibits PBMs from owning pharmacies in the state. In light of the Iowa and Arkansas challenges, the Fair RX Act includes a narrow carve-out for military and federal contracts to avoid TRICARE preemption.

Nonetheless, three separate lawsuits have been filed in the U.S. District Court for the Middle District of Tennessee by Caremark, Express Scripts, and the Pharmaceutical Care Management Association, arguing that the Fair RX Act (1) is preempted by Medicare, TRICARE, and ERISA; (2) violates the dormant Commerce Clause by discriminating against out-of-state pharmacies; and (3) violates the Takings Clause by compelling divestiture of PBMs' pharmacy units. Decisions on each remain outstanding.

**Implications for Further State and Federal Reform**

PBM reforms are evolving quickly, with major PBMs and their stakeholders seeking to influence the state-level regulatory landscape through constitutional challenges. If the challenges to Tennessee's Fair RX Act are unsuccessful, other states may pursue similar legislation, potentially limiting PBM-affiliated or -owned pharmacies; instituting geographic coverage requirements; or expanding "any willing pharmacy" rules beyond Medicare.

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