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Legal Sidebar

# Pharmacy Benefit Managers: Current Legal Framework

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Several bills introduced in the 118th Congress address the rising cost of prescription drugs for American consumers. Some of these proposals concern the role of pharmacy benefit managers (PBMs), which facilitate the purchase of drugs through the pharmaceutical distribution chain and administer pharmacy benefit plans on behalf of health insurers, employers, and others. This Legal Sidebar provides a brief overview of PBMs' key functions, selected federal and state laws that regulate these entities, and issues surrounding federal preemption of state laws addressing PBMs. Federal Trade Commission (FTC) oversight of PBMs is also addressed, and the Sidebar concludes with a sampling of legislative proposals that address PBM business practices at the federal level, including by placing limitations on spread pricing, increasing cost transparency, and increasing oversight by the FTC and Department of Health and Human Services (HHS).

## Introduction to PBMs

Most health insurance plans include prescription drug benefits that help enrollees pay for the cost of drugs prescribed as part of their care. Prescription drug plans typically include formularies (which list the plan's covered drugs) and specify different levels of enrollee prescription cost-sharing for drug "tiers," ranging from low-cost generics to more expensive specialty drugs. Enrollees generally fill prescriptions at network pharmacies that have contracted with health care payers to dispense the drugs for a set payment.

Health care payers, which may include private health insurance plans or government health programs like Medicare Part D or Medicaid, may contract with PBMs to design and administer prescription drug benefit plans. In doing so, PBMs design drug formularies, negotiate prescription drug prices with manufacturers, and contract with network pharmacies. PBMs also operate electronic systems that process prescription drug claims, calculate enrollee out-of-pocket costs, and reimburse pharmacies for drugs dispensed to enrollees.

In recent years, vertical integration of PBMs has led to many PBMs being owned by or affiliated with pharmacy chains, insurance companies, and health care providers. In 2022, the three largest PBMs (CVS Caremark, part of CVS Health, which owns Anthem; Express Scripts, which is owned by Cigna; and OptumRx, which is owned by UnitedHealthcare) processed a large majority of prescription drug claims in

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the United States. This gives PBMs considerable leverage with health payers, pharmacies, and drug manufacturers. According to the Pharmaceutical Care Management Association, a trade association representing the PBM industry, more than 275 million Americans receive PBM services.

PBM contracts with payers can specify different methods of compensation, including administrative fees for claims processing and other services. Where allowed, PBMs may engage in a practice known as spread pricing, whereby the PBM generates profit by reimbursing a pharmacy at a lower rate than the amount the PBM is paid by the health payer. PBMs may also generate fees for dispensing drugs through retail and mail-order pharmacies. Some contracts allow PBMs to keep a portion of savings generated from negotiations with drug manufacturers, rather than passing on such savings to the health payer. PBMs also generate revenue by dispensing drugs from their own mail-order and specialty drug pharmacies, rather than through contracted health plan network pharmacies.

Some federal laws and regulations directly regulate PBM practices. For example, section 1150A of the Social Security Act imposes reporting requirements on PBMs administering Medicare Part D and some private health insurance plans. These requirements relate to PBM transparency and require PBMs to disclose certain information to the HHS Secretary (e.g., the number of prescriptions filled and the aggregate amount of rebates, discounts, and other price concessions). Similarly, section 2729 of the Public Health Service Act, which applies to PBMs administering benefits for some private health plans, prohibits gag clauses, meaning that PBMs cannot restrict retail pharmacies from disclosing out-of-pocket cost information to patients. In addition, PBMs are subject to general antitrust and consumer protection laws, including the FTC Act.

# State Law Regulation of PBMs

Against the backdrop of limited federal PBM regulation, many states have sought to address PBM practices. States have taken different approaches to regulating PBMs, and state laws vary in their scope and applicability. While some apply only in the context of private health insurance coverage, others may also apply to government health programs. This section focuses generally on the types of state proposals, rather than their specific applicability, identifying several recent themes. Some state laws have led to litigation, including the cases discussed below, while others have not been challenged. According to the National Academy for State Health Policy, all 50 states have now enacted at least one law that addresses PBMs. In 2023 alone, at least 43 states considered PBM reform bills, and more than 20 state laws have been enacted.

According to one recent report, at least 44 states have enacted laws that prohibit PBMs from subjecting their contract pharmacies to gag clauses, meaning that a PBM's contract with a pharmacy cannot prevent pharmacy employees from disclosing certain drug pricing information to patients. Such information includes the existence of therapeutic equivalents that are offered at a lower cost or other information about lowering the cost of the medication (e.g., through cash discounts). Florida's S.B. 1550, enacted in 2023, prohibits PBMs from including gag clauses in pharmacy contracts. New Jersey's law, A. 536, enacted in 2022, bans gag clauses that stop pharmacists from communicating with patients about the existence of cash discounts.

More than half of states have enacted laws generally requiring PBMs to be licensed or registered through a state agency before they can transact business in that state. In 2023, both New Jersey (A. 536) and South Dakota (H.B. 1135) enacted licensing requirements for PBMs operating in their state. These laws can provide states an additional enforcement mechanism for their rules. For example, South Dakota may now revoke a PBM's business license if the PBM fails to comply with the state's new PBM law. New Jersey's law appears even broader, allowing the state to revoke a PBM's license if the PBM engages in "fraudulent activity," or any other activity that violates federal or state law.

Some states have also prohibited PBMs from engaging in spread pricing. This means that the PBM cannot charge a health plan more for an outpatient prescription drug than the amount that the PBM reimburses the pharmacy. Florida, for example, has banned spread pricing unless the PBM passes the "entire amount of such difference" to the health payer. The state further requires PBMs to use a "pass-through pricing model," in which the price that the plan or program pays to the PBM is equivalent to the PBM's payment to the pharmacy. A few states also require PBMs to report their profits to a state agency for oversight purposes.

Some states have also determined that PBMs should owe a fiduciary duty to the health payer, as the PBM can act as the plan's agent through the administration of the plan's drug benefits. States like New Jersey, Vermont, and Tennessee currently impose fiduciary duties on PBMs. The New Jersey law, enacted in 2023, also requires a PBM to act in "good faith and fair dealing in the performance of all of its contractual duties."

Finally, a few states have attempted to stop PBMs from allegedly discriminating against 340B covered entities, which can occur if a PBM offers a covered entity a lower reimbursement rate for dispensing a drug than a non-340B entity. In 2023, a few states enacted provisions to stop covered entities from receiving lower PBM reimbursements, including Iowa (H.F. 423), Nevada (A.B. 434), and Oregon (H.B. 2725).

# State PBM Regulation and Federal Preemption Challenges

As states have enacted legislation intended to regulate certain PBM practices, PBMs and their advocates have challenged some state measures on the basis that they are allegedly preempted by federal law, including the Employee Retirement Income Security Act (ERISA), particularly in the context of private-sector health coverage. ERISA regulates private-sector employee benefit plans, and an express preemption clause in the Act specifies that ERISA broadly supersedes state laws that "relate to" such plans. In numerous opinions, the Supreme Court has interpreted the "relate to" language as applying to any state law that "has a connection with or reference to [an employee benefit] plan," and has concluded ERISA may displace state laws that, for example, aim to regulate plan benefits, or the administration, operation, or structure of plans. PBM advocates have claimed that certain state laws regulating PBM practices are preempted by ERISA, in part because the laws have a direct regulatory effect on ERISA-governed plans, plan design, and how these plans manage drug benefits.

In 2021, the Supreme Court addressed the interplay between a state's PBM laws and ERISA preemption in *Rutledge v. Pharmaceutical Care Management Association (PCMA)*. In this case, the Court examined the validity of an Arkansas statute generally designed to tether PBM pharmacy reimbursement rates to pharmacies' acquisition costs, and it concluded that the state law survived federal preemption. As the Court explained, state laws that "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage" fall beyond the Act's preemptive reach. However, consistent with other ERISA preemption decisions, the Court recognized limits on this flexibility and generally explained that state laws cannot compel ERISA plans to offer a certain type of coverage or administer benefits in a particular manner.

In the wake of *Rutledge*, questions of whether a state's law permissibly regulates PBMs or improperly "dictate[s] plan choices" continue to be the subject of litigation. For instance, in August 2023, the U.S. Court of Appeals for the Tenth Circuit in *PCMA v. Mulready* invalidated an Oklahoma law compelling PBMs to comply with certain pharmacy network standards, holding that ERISA and the Medicare statute preempted the state law. With respect to ERISA, the appeals court explained that the state law was superseded because it generally compelled ERISA plans to structure benefits in certain ways. Following

the Tenth Circuit's decision, Oklahoma's Attorney General filed a petition for rehearing before the full Tenth Circuit and has mentioned the possibility of appealing to the Supreme Court.

# FTC Action Related to PBMs

The FTC, which enforces a variety of federal antitrust and consumer protection laws, has also recently displayed a substantial interest in PBMs, resulting in an ongoing study of the industry under Section 6(b) of the FTC Act, a June 2022 policy statement regarding pharmaceutical rebates and fees, and a July 2023 statement withdrawing certain earlier FTC advocacy statements and studies concerning PBMs.

In June 2022, the FTC launched an inquiry into PBMs under its general Section 6(b) authority, following debate among the Commissioners and the solicitation of public comments on PBM business practices. Section 6(b) authorizes the FTC to require answers in writing from entities to specific questions concerning business practices and enables the FTC to conduct studies without a specific law enforcement purpose. The FTC initially required responses from the six largest PBMs. In May and June 2023, the FTC issued further orders requiring responses from three group purchasing organizations, which negotiate rebates from manufacturers on behalf of PBMs. The inquiry remains ongoing.

Shortly after initiating the Section 6(b) study, the FTC issued an enforcement policy statement regarding rebate and fee practices. The FTC stated that such practices could constitute unlawful conduct if they stifle or foreclose competition by incentivizing PBMs and other intermediaries to steer patients away from less expensive alternatives to higher-cost drugs. The FTC reasoned that such conduct could violate the Sherman Act, Section 3 of the Clayton Act, Section 5 of the FTC Act, and Section 2(c) of the Robinson-Patman Act.

In July 2023, the FTC issued a statement cautioning against reliance on FTC advocacy letters and reports published between 2004 and 2014. Those documents took the position that state and federal efforts to mandate transparency from PBMs could undermine competitive processes. The FTC expressed concern that industry advocates continued to cite these documents despite intervening significant changes in the PBM industry and the FTC's ongoing Section 6(b) study into current market conditions.

# Considerations for Congress

The PBMs' value-add in administering health benefit plans is debated, with some stakeholders claiming that PBMs are vital to patient cost savings, and others arguing that PBM practices contribute to higher U.S. drug prices by increasing costs and designing formularies that include drugs with higher rebates even if they are more expensive to consumers. A variety of legislative proposals offered in the 118th Congress would regulate aspects of the PBM industry. Some bills seek to increase transparency in PBM business practices, end spread pricing, or more generally cut consumer prescription drug costs. Other proposals have focused on regulating PBM activities as tied to a particular sector, such Medicare or private health insurance. Both House and Senate Committees have proposed various bipartisan PBM reform bills.

Among these proposals, S. 127, the Pharmacy Benefit Manager Transparency Act of 2023, as ordered to be reported from the Senate Committee on Commerce, Science, and Transportation, proposes to ban PBM spread pricing, including charging payers a different amount than the PBM will reimburse, clawing back reimbursement payments, or otherwise offsetting reimbursement amounts. The bill would also create pricing transparency requirements, and authorizes the FTC and state attorneys general to enforce its provisions by seeking civil money penalties from PBMs who violate its requirements. H.R. 5378, the Lower Costs, More Transparency Act, seeks to increase price transparency across the health care industry, including by imposing requirements on hospitals and other Medicare participating providers, as well as PBMs. The bill also proposes to require pass-through pricing models for PBMs that administer Medicaid prescription drug benefits.

Other proposals have called for the FTC to become more involved in studying PBMs and enforcing potential violations of antitrust and consumer protection laws. For example, S. 113, the PBM Prescription Pricing for the People Act, would require the FTC to issue a report examining PBM business practices, including formulary designs, incentives for patients to use PBM-owned pharmacies, and charging certain payers higher prices. The legislation also calls for the FTC to evaluate the state drug supply chain and assess whether additional information would benefit consumers. While the FTC is pursuing the ongoing Section 6(b) study on PBMs, the bill would impose specific reporting, content, and timing requirements.

If lawmakers seek greater policy diversity and experimentation at the state level, they could also modify the scope of ERISA preemption to authorize further state regulation of PBMs. As discussed earlier, while many states have attempted to regulate PBMs, some of these measures have been challenged on preemption grounds. Additionally, given the breadth of state action thus far, lawmakers may also clarify the extent to which any new federal PBM legislation would preempt existing state law.

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