



March 2024

PRESCRIPTION DRUGS

Selected States' Regulation of Pharmacy Benefit Managers

Why GAO Did This Study

Prescription drug spending by private health plans climbed to nearly \$152 billion in 2021, an 18 percent increase from 2016. Health plans generally rely on PBMs to process claims, develop pharmacy networks, and negotiate rebates from drug manufacturers. However, some researchers and stakeholders have questioned certain PBM practices, such as PBMs retaining a share of the rebates and use of spread pricing. In response, states have begun to enact legislation addressing PBMs, with all 50 states having enacted at least one PBM-related law between 2017 and 2023.

GAO was asked to review states' regulation of PBMs serving private health plans. Among other things, this report describes actions selected states have taken to regulate PBMs, and lessons learned that state regulators identified for PBM regulation.

GAO focused on a selection of five states that have enacted a wide range of PBM laws, based on existing inventories maintained by national policy research organizations, such as the National Conference of State Legislatures. GAO reviewed states' laws and interviewed state regulators as well as a variety of other stakeholders. These included state pharmacy associations and state health plan associations in each of the five states, and four national organizations representing interests of PBMs, patients, employers, and drug manufacturers, respectively.

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What GAO Found

Private health plans contract with pharmacy benefit managers (PBM) to administer their prescription drug benefits and help control costs. Each of the five states selected for review—Arkansas, California, Louisiana, Maine, and New York—enacted a variety of laws to regulate PBMs.

- **Fiduciary or other “duty of care” requirements.** Four of the five states (California, Louisiana, Maine, and New York) enacted laws to impose a duty of care on PBMs. The laws varied from imposing a fiduciary duty—that is, a requirement to act in the best interest of the health plan or other entity to which the duty is owed—to what state regulators described as “lesser” standards such as a requirement to act in “good faith and fair dealing.”
- **Drug pricing and pharmacy reimbursement requirements.** The five states enacted a variety of laws relating to drug pricing and pharmacy payments, such as laws limiting PBMs' use of manufacturer rebates and their ability to pay pharmacies less than they charge health plans—a practice referred to as “spread pricing.”
- **Transparency, including licensure and reporting requirements.** To increase the transparency of PBM operations, the five states enacted laws that require PBMs to be licensed by or registered with the state, or both, and to report certain information such as drug pricing, fees charged, and the amounts of rebates received and retained.
- **Pharmacy network and access requirements.** The five states also enacted laws regarding pharmacy networks and patient access. Examples include laws prohibiting discrimination against unaffiliated pharmacies and limiting patient co-pays charged by PBMs.

The regulators GAO interviewed from selected states described lessons learned regarding PBM regulation. Examples include the following.

- Regulators in four states said that providing regulators with broad regulatory authority was more effective than enacting specific statutory provisions. Doing so allowed regulators to address emerging issues without new legislation, according to regulators from one state.
- Some regulators also stressed the need for robust enforcement of PBM laws and effective penalties to enforce them. Two pharmacy associations GAO interviewed concurred with these views, while a health plan association said that monitoring is needed to ensure compliance with PBM requirements. Three regulators also said that clear reporting requirements and definitions helped ensure consistent enforcement.

The Department of Labor provided technical comments on a draft copy of this report, which GAO incorporated as appropriate.

Contents

Letter		1
	Background	4
	States We Reviewed Have Enacted a Variety of Laws to Regulate PBMs	10
	Stakeholders Expressed Mixed Views on Selected State Actions to Regulate PBMs	17
	State Regulators Identified Lessons Such as Providing Broad State Regulatory Authority and Robust Enforcement Powers	22
	Agency Comments	26
Appendix I	Stakeholders Interviewed by GAO	28
Appendix II	Stakeholders Views on Areas of State Pharmacy Benefit Manager (PBM) Regulation in Five Selected States	29
Appendix III	GAO Contact and Staff Acknowledgments	34
Tables		
	Table 1: Selected State-Level Actions to Regulate Pharmacy Benefit Managers (PBMs) Serving Private, Employer-Sponsored Health Plans, as of November 2023	16
	Table 2: Stakeholder Positions on Areas of Pharmacy Benefit Manager (PBM) Regulation	20
	Table 3: Examples of Comments Offered by Stakeholders Regarding Areas of State Pharmacy Benefit Manager (PBM) Regulation	21
Figure		
	Figure 1: Example of the Flow of Funds and Prescription Drugs through the Supply Chain When a Health Plan Member Purchases a Drug through a Pharmacy Benefit Manager (PBM)	9

Abbreviations

ERISA	Employee Retirement Income Security Act of 1974
MAC	maximum allowable cost
PBM	pharmacy benefit manager

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March 18, 2024

The Honorable Virginia Foxx
Chairwoman
Committee on Education and the Workforce
House of Representatives

The Honorable Bob Good
Chairman
Subcommittee on Health, Employment, Labor, and Pensions
Committee on Education and the Workforce
House of Representatives

The Honorable Rick Allen
House of Representatives

The Honorable Diana Harshbarger
House of Representatives

Retail prescription drug spending by private health plans in the U.S. totaled nearly \$152 billion in 2021—almost 13 percent of total private health care spending and an almost 18 percent increase over 2016.¹ To help manage rising prescription drug costs, private health plans generally contract with pharmacy benefit managers (PBM) to administer their pharmacy benefits. PBMs may negotiate prices or rebates with drug manufacturers, develop networks of pharmacies and negotiate prices paid to pharmacies for dispensing drugs to plan enrollees, and adjudicate claims.

Researchers and various stakeholders have noted advantages of, but have also raised questions about, the services that pharmacy benefit managers provide.² Some health plans and the PBM trade association

¹Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, *Table 16: Retail Prescription Drugs Expenditures: Levels, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years 1970-2021* (Baltimore, MD.: 2022). This figure does not include out-of-pocket expenses (i.e., expenditures not covered by insurance) or non-retail prescriptions (e.g., those dispensed in hospitals or physicians' offices).

²See, for example, T. Joseph Mattingly, David A. Hyman and Ge Bai, "Pharmacy Benefit Managers: History, Business Practice, Economics, and Policy," *JAMA Health Forum*, vol. 4, no. 11 (2023).

have generally noted that PBMs' market power enables them to directly negotiate rebates with manufacturers to lower prescription drug costs for enrollees and health plans. They also highlight the other functions that PBMs provide, such as promoting generic substitution, improving patients' drug adherence, and identifying possible adverse drug reactions. However, an employer organization, a pharmacy association, and a patient advocacy organization have raised questions about whether pharmacy benefit managers have too much market power, and whether PBM arrangements are too complex and opaque, making it difficult to identify all their sources of revenue. For example, PBMs may derive their revenue from various sources including retention of some manufacturer rebates, administrative fees charged to health plans, and the spread between what they pay pharmacies to dispense drugs and what they charge health plans. According to the Commonwealth Fund, some of these revenue sources are generally kept confidential even from the health plans that hire the PBMs.

Trends in the industry have also raised concerns about the market power of pharmacy benefit managers. Consolidation among PBMs has resulted in the three largest PBMs processing approximately 79 percent of all prescription drugs in 2022.³ Another trend which also increases PBM market power is their vertical integration with other entities. The Federal Trade Commission announced an inquiry in 2022, which is ongoing as of January 2024, intended to assess the effect of vertical integration on the access to and affordability of prescription drugs, noting that the three largest PBMs are each integrated with both a health insurer and wholly owned mail order and specialty pharmacies.⁴

States, as the primary regulators of private health insurance, have taken actions to regulate PBMs to lower prescription drug costs and address some of their concerns about PBM business practices. You asked us to review states' actions to regulate PBMs serving private health plans. In this report we describe:

1. actions selected states have taken to regulate PBMs,

³Additionally, the six largest PBMs control 96 percent of the market, according to one source. See Drug Channels Institute, *The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies* (Philadelphia, PA: 2023).

⁴Federal Trade Commission, "FTC Launches Inquiry Into Prescription Drug Middlemen Industry" (June 7, 2022), accessed March 15, 2023, <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>.

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2. selected stakeholders' views of these actions, and
 3. lessons for PBM regulation identified by state regulators.

For all three objectives, we focused on a nongeneralizable selection of five states with experience implementing state laws affecting PBM business practices. To select states, we first reviewed existing inventories of state PBM laws maintained by three national policy research organizations to identify states that had enacted a wide range of PBM laws.⁵ We also considered geographic diversity to the extent possible. Based on these criteria we selected five states: Arkansas, California, Louisiana, Maine, and New York.

To describe actions that the five selected states have taken to regulate PBMs, we reviewed state laws and related documents. We also interviewed state regulators from the primary oversight agency (e.g., state departments of insurance) to discuss the PBM laws passed by their legislatures and the implementation of these laws.

To describe stakeholder views of states' actions to regulate PBMs and any lessons learned from stakeholders about PBM regulation, we interviewed the state health plan association and state pharmacy association in each selected state, in addition to the state regulators.⁶ To augment these perspectives, we also interviewed four national organizations, including the trade association representing PBMs and three national advocacy organizations representing employers' interests, patient interests, and pharmaceutical manufacturers. See appendix I for a list of the stakeholders we interviewed.

We conducted this performance audit from June 2023 through March 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to

⁵The three organizations were National Academy for State Health Policy, National Conference of State Legislators, and National Association of Insurance Commissioners. Compendia of state laws are available on the organizations' websites at <https://nashp.org/state-drug-pricing-laws-2017-2023>, <https://www.ncsl.org/health/prescription-drug-state-bill-tracking-database-2015-present>, and <https://content.naic.org/cjpr-topics/pharmacy-benefit-managers>, respectively (accessed December 4, 2023).

⁶In one state where there was no health plan association, we instead interviewed the state's largest insurer that covered 86 percent of individuals in the state in 2022. For simplicity, in some cases we use the term health plan association for this insurer in the report.

obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our finding and conclusions based on our audit objectives.

Background

Overview of Private, Employer-Sponsored Health Coverage

Nearly half of the population in the U.S.—about 158 million individuals—receives health coverage through private health plans sponsored by their employers.⁷ Generally, employers provide health coverage in two ways. They may purchase coverage from state-regulated issuers on behalf of their employees (also known as fully insured plans). Alternately, they can self-fund their plans (also known as self-insured plans)—that is, they pay directly for at least some of their employees' health care costs and typically contract with an issuer or other company to administer benefits and process claims. In 2022, about 65 percent of covered employees were in self-insured plans.⁸

Regulation of Private, Employer Sponsored Health Coverage and PBMs

Both states and the federal government have regulatory roles in private health coverage. The federal government, led by the Department of Labor, regulates private employer-sponsored health plans under the Employee Retirement Income Security Act of 1974 (ERISA), which sets minimum standards for group health plans, both fully insured and self-insured. Among these standards are claims and appeals processes, reporting and disclosure requirements, and fiduciary responsibilities for those who administer the plan and its assets.⁹

⁷Kaiser Family Foundation, *Health Insurance Coverage of the Total Population, 2022* (San Francisco, CA: 2023). In addition, about another 20 million individuals purchased health coverage through private health plans as individuals, outside of the workplace. These estimates are based on the 2008-2022 American Community Survey.

In general, those who obtain private health coverage do so in the individual or group market. The individual market includes plans purchased directly from an insurer, while the group market—which includes small and large groups—is largely made up of employer-sponsored plans.

⁸See Kaiser Family Foundation, *Employer Health Benefits 2022 Annual Survey* (San Francisco, CA: October 2022).

⁹A fiduciary is required to act in the best interest of the entity (e.g., health plan) to which the duty is owed. ERISA requires fiduciaries to act prudently and solely in the interest of health plan participants and beneficiaries. Group health plans are also subject to certain health care reforms and consumer protections, including those added by the Patient Protection and Affordable Care Act, No Surprises Act, and Mental Health Parity and Addiction Equity Act of 2008.

States are the primary regulators of health insurance issuers. Health plans offered by state regulated issuers, including fully insured plans, are subject to both state and federal requirements.¹⁰ Each state’s insurance department enforces the states’ insurance laws and regulations. State insurance departments typically manage the licensing of issuers and agents selling insurance products. Additionally, states regulate issuers’ financial operations to ensure funds are adequate to pay claims, review premium rates, and implement consumer protections such as claims appeals processes.

ERISA preempts state laws that “relate to” any employee benefit plan and has been interpreted by courts to restrict the extent to which states can regulate self-insured plans.¹¹ For example, self-insured plans are not required to comply with state-mandated benefit requirements, such as coverage of certain benefits or procedures. Therefore, an advantage of self-insured plans to large, multi-state employers is the ability to offer a uniform benefit package across different locations, as long as it complies with ERISA requirements. While ERISA generally limits states’ ability to regulate self-insured plans, the Supreme Court has ruled that states may impose certain regulatory requirements that do not have an impermissible connection or impermissible reference to an ERISA plan.¹² 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 how ERISA-governed plans manage drug benefits.¹³

As the role of PBMs has grown from that of processing claims to a larger role in fully administering drug benefits and negotiating prices along the pharmaceutical supply chain, states have begun to regulate PBMs. According to a few stakeholders, states have taken different approaches to regulating PBMs as, among other factors, oversight and enforcement

¹⁰Issuers are entities licensed by a state to engage in the business of health insurance in that specific state.

¹¹Under ERISA, states retain the authority to regulate issuers. Therefore, a fully insured health plan, where an employer purchases health coverage from an issuer, is regulated by state insurance laws (through state regulation of the issuer) and ERISA (through federal regulation of the plan).

¹²See, for example, *Gobeille v. Liberty Mut. Ins. Co.*, 577 U. S. 312 (2016); *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U. S. 645 (1995). More recently, the Supreme Court held that ERISA does not preempt an Arkansas law regulating PBM reimbursement to pharmacies. *Rutledge v. Pharm. Care Mgmt. Assoc.*, 141 S. Ct. 474 (2020).

¹³See *Pharm. Care Mgmt. Assoc. v. Mulready*, No. 22-6074 (10th Cir. 2023).

authority may be divided among different departments or laws within a state. For example, a state’s insurance department may license PBMs as third-party administrators under its insurance law; PBM duties of care may be specified under its public health and safety law; and enforcement authority may rest with a different entity, such as the Attorney General’s office. According to one group tracking PBM legislation at the state level, between 2017 and 2023, all 50 states had enacted at least one law regulating PBM business practices. These laws have included licensure and registration requirements, mandated transparency reporting, and requirements regarding consumer protections and pharmacy reimbursement.¹⁴

Overview of Prescription Drug Spending Trends

Prescription drug spending has consistently grown over the past decade, prompting health plans to seek ways to better manage these costs. Retail prescription drug expenditures by private health plans grew from \$129.1 billion to nearly \$152 billion between 2016 and 2021, an increase of approximately 18 percent.¹⁵

The main driver of that growth is increased prescription drug prices, as opposed to increased prescription drug utilization (i.e., the number of prescriptions filled). While retail prescription drug spending grew by 13 percent between 2016 and 2021, retail prescription drug utilization only increased by 5.7 percent in this same period. The increase in spending is driven in part by growing spending on high-cost prescription drugs known as specialty drugs.¹⁶ In 2021, specialty drugs comprised 15.4 percent of retail prescriptions but represented 41.8 percent of retail prescription spending. Additionally, retail specialty drug prescriptions declined by 18.3 percent between 2016 and 2021, while retail spending on specialty drugs increased by 21.9 percent in the same period.

¹⁴National Academy for State Health Policy, “State Tracker: State Pharmacy Benefit Manager Legislation, 2017-2023” (Washington, DC: November 2023), accessed November 3, 2023, <https://nashp.org/state-pharmacy-benefit-manager-legislation>.

¹⁵Department of Health and Human Services, Assistant Secretary for Planning and Evaluation (ASPE), Office of Science & Data Policy. *Trends in Prescription Drug Spending, 2016-2021* (Washington, DC: 2022).

Retail drugs are defined as those filled in an outpatient setting such as standalone pharmacies or mail order prescriptions. Non-retail drugs are those administered in an inpatient setting such as a hospital, clinic, or physician office.

¹⁶The data used by ASPE defines specialty drugs as generally high-cost products used to treat complex, rare, or chronic disease. See Department of Health and Human Services, *Trends in Prescription Drug Spending, 2016-2021*.

Private Health Plans' Use of PBMs

Many health plans contract with PBMs to manage prescription drug benefits. The Pharmaceutical Care Management Association (PCMA), a PBM trade association, reports that more than 275 million Americans receive prescription drug benefits through PBMs across several insurance markets including employer-sponsored plans, Medicaid, and Medicare Part D. There are over 60 PBMs in the United States, but a large majority of prescription drug claims are processed by just three: CVS Health/Caremark, Cigna/Evernorth/Express Scripts, and United Health/OptumRx.

Pharmacy benefit managers offer services that reduce the complexity of administering prescription drug benefits and negotiate rebates with manufacturers to reduce the overall cost of prescription drugs. PBMs generally handle rebate negotiations, claims processing, and payments at various points within the pharmaceutical drug supply chain (see fig. 1). Additionally, some PBMs have a direct role in the physical distribution of prescription drugs.¹⁷

Pharmacy benefit managers receive compensation from health plans for their services in a variety of ways. Health plans may opt for an administrative fee contract, where they pay the PBM directly for all the services provided. Alternatively, health plans may elect to use a spread pricing option. Under spread pricing, the health plan pays the PBM a set price for each prescription filled, and the PBM retains the difference between the price paid by the health plan and the price paid to the pharmacy as a form of compensation. Additionally, PBMs may retain a portion of manufacturer rebates to offset the fees health plans would otherwise pay.

PBMs provide the following services within the pharmaceutical supply chain.

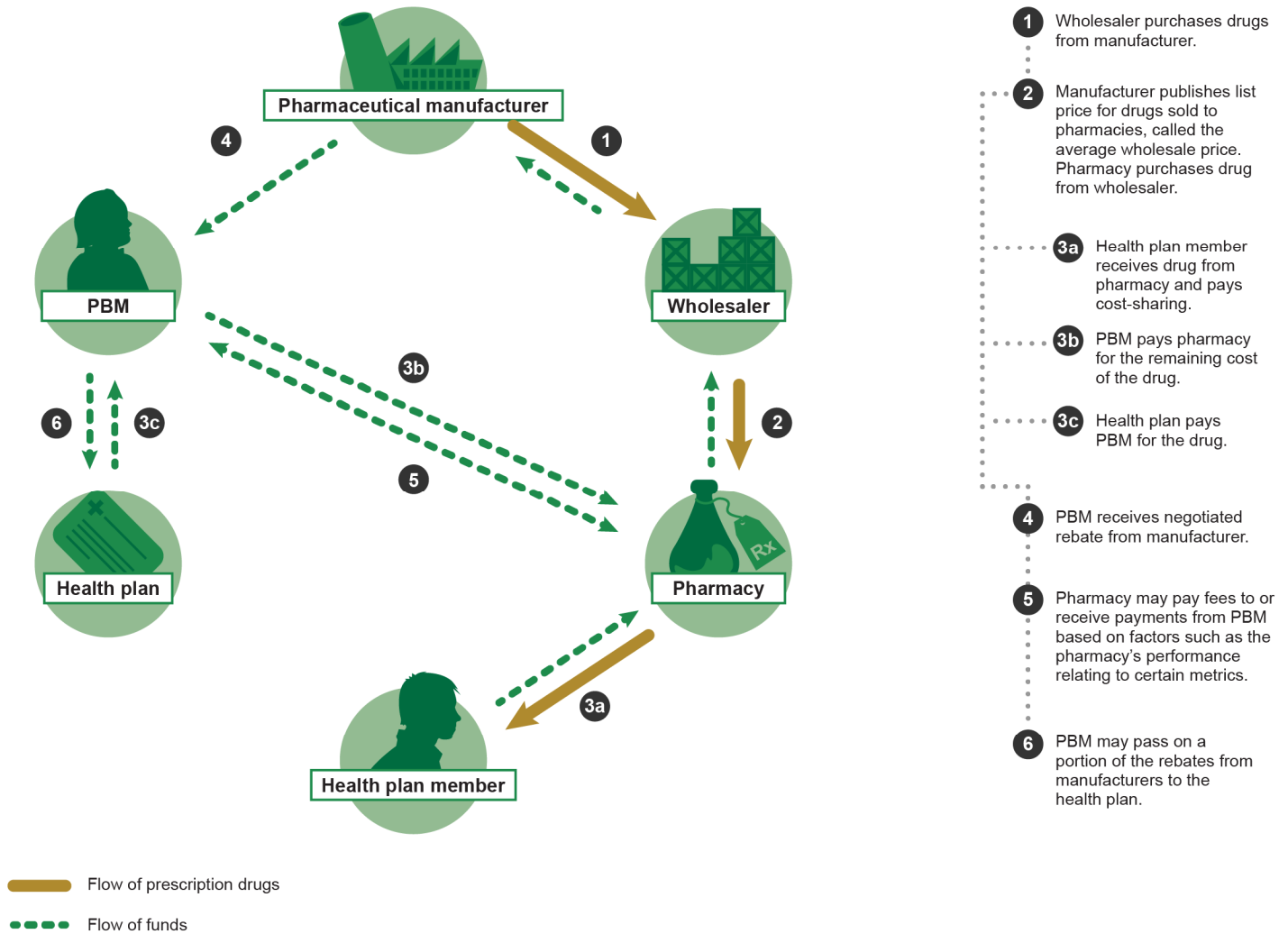
- **Rebate negotiation and formulary development.** The number of covered individuals receiving prescription drug benefits through PBMs gives PBMs power to negotiate with pharmaceutical manufacturers. PBMs use this to negotiate rebates with pharmaceutical manufacturers—generally for brand-name and specialty drugs—in exchange for placement on health plans' formularies. Rebates are

¹⁷While PBMs generally do not have a direct role in the physical distribution of prescription drugs, some PBMs operate mail order pharmacies or specialty drug facilities to fill prescriptions. The largest PBMs are fully vertically integrated with the largest health insurers and wholly owned mail order and specialty pharmacies.

applied after sales, and PBMs may pass some of these rebates on to health plans to reduce premiums for plan beneficiaries.

- **Pharmacy network development.** PBMs negotiate drug prices and reimbursements with pharmacies to create networks where plan members can fill prescriptions. Enrollees have incentives to use in-network pharmacies as they typically offer lower out-of-pocket costs compared to out-of-network pharmacies.
- **Utilization management.** PBMs assist health plans in administering and monitoring patient drug utilization. This includes actions such as step therapy, a requirement where patients must first try less expensive alternatives before moving onto a more expensive drug their physician initially prescribed. Another example is prior authorization, where patients must receive approval before obtaining a particular drug.
- **Claims processing.** PBMs process claims filed by pharmacies and adjudicate claims on behalf of health plans.

Figure 1: Example of the Flow of Funds and Prescription Drugs through the Supply Chain When a Health Plan Member Purchases a Drug through a Pharmacy Benefit Manager (PBM)



Source: GAO (icons and information). | GAO-24-106898

Duty of Care Provisions and Fiduciary Duty

According to a few stakeholders, health plans generally include a “duty of care” provision or clause in their contracts with pharmacy benefit managers, which typically require PBMs to perform their specified duties with good faith and in accordance with the terms of their contract. According to one state regulatory agency, health plans may terminate their PBM contracts if the PBM breaches this duty. However, some states have imposed additional duties of care on PBMs beyond those specified in their contracts with health plans. One type of duty of care is a fiduciary

duty, which requires PBMs to act in the best interests, and protect the financial interests, of the party to which they owe the duty, such as their health plan clients. Fiduciaries may be held liable for restoring losses to the plan or returning profits gained through improper use of plan assets.

States We Reviewed Have Enacted a Variety of Laws to Regulate PBMs

The five selected states enacted a wide range of laws to regulate PBMs, including imposing duty of care requirements and other policies related to drug pricing and pharmacy reimbursement, transparency reporting, and enrollee access to pharmacy networks. These laws apply to PBMs serving fully insured plans, and, depending on the state and type of law, may also apply to PBMs serving self-insured plans.¹⁸

Four of Five Selected States Imposed a Duty of Care on PBMs, but States Took Different Approaches

Four of the five selected states imposed a duty of care on PBMs to the health plans for which they administered pharmacy benefits.

- **Maine.** Maine’s law states that PBMs are agents of, and owe a fiduciary duty to, the health plans with which they contract.¹⁹ Plans are responsible for ensuring PBMs comply with these and other contract terms.²⁰
- **California, New York, and Louisiana.** Laws in California, Louisiana, and New York impose some version of a duty of good faith on PBMs. California requires PBMs to exercise “good faith and fair dealing.”²¹ New York requires PBMs to act with “care, skill, prudence, diligence, and professionalism” and imposes a duty of good faith and fair dealing to all parties with whom they interact in the performance of PBM services.²² Louisiana establishes “the duties of good faith, honesty,

¹⁸Arkansas officials told us that, except for the Maximum Allowable Cost (MAC) list provision, they do not enforce PBM laws against pharmacy benefit managers that only serve self-insured plans. California officials told us that their PBM laws do not apply to pharmacy benefit managers serving self-insured plans. Louisiana officials told us that their PBM laws do not specifically address self-insured plans. Maine officials told us the only PBM laws that apply to pharmacy benefit managers serving self-insured plans are the licensing and reporting requirements. New York officials told us their PBM laws apply to all pharmacy benefit managers regardless of the type of plan they serve.

In some states, these laws may also apply to PBMs serving other plans such as Medicaid, which are beyond the scope of this report.

¹⁹24-A M.R.S. § 4349(2).

²⁰24-A M.R.S. § 4349(1)-(2).

²¹CA Bus. & Prof. Code § 4441(c).

²²N.Y. Pub. Health Law § 280-a(2).

trust, confidence, and candor” for PBMs.²³ Laws in two states—Louisiana and New York—specify that the PBMs’ duty of care is to both health plans and enrollees.

- **Arkansas.** This state does not impose a specific duty of care on PBMs. State regulators told us that, after a bill that included a fiduciary requirement failed to pass, legislators thought existing state PBM regulations were sufficient, and an additional duty of care standard was not required.

Selected States’ Requirements for PBMs on Drug Pricing and Pharmacy Reimbursement, Transparency, and Access

The five selected states have taken a range of other actions to regulate PBMs. Three states—Arkansas, Louisiana, and Maine—have implemented several provisions relating to drug pricing and pharmacy reimbursement. California regulators told us that their legislature has generally not enacted PBM-related legislation regarding drug pricing and reimbursement that would affect health plans under their purview, with the exception of a maximum allowable cost (MAC) law.²⁴ New York officials told us that state regulators are in the process of promulgating regulations to implement recently enacted PBM legislation. However, all five states have imposed licensure, registration (including transparency and/or reporting), or access requirements for PBMs.

Drug pricing and pharmacy reimbursement requirements. Four of the five states have implemented provisions governing PBMs’ usage of rebates, spread pricing, retroactive payment adjustments to pharmacies, reimbursement of pharmacies, or MAC lists.

- **Rebate usage.** Two of the five states regulate PBMs’ use of manufacturer rebates. Maine requires that PBMs either remit all rebates to enrollees at the point of sale or remit them to the issuer, in which case the issuer is required to use those funds to reduce premiums or out-of-pocket costs for enrollees.²⁵ Arkansas requires

²³LA Rev. Stat. § 40:2864.

²⁴According to California regulators, the primary law governing state oversight of managed health care provides the department authority to oversee health plans in the state, including contractual relationships with PBMs, but the law does not establish direct oversight over PBMs. A stakeholder told us there are forty-four plans in California under the purview of the Department of Managed Health Care, representing primarily health maintenance organizations but also some traditional insurers. Roughly three to five percent of other health plans, primarily traditional insurers, are governed by the California Department of Insurance.

²⁵24-A M.R.S. § 4350-A.

that PBMs and health plans set enrollee cost-sharing amounts for prescription drugs based on post-rebate prices.²⁶

- **Spread pricing.** Two of the five states enacted legislation addressing PBMs' use of spread pricing—a practice in which PBMs reimburse pharmacies at one rate and charge plans a different rate, retaining any positive difference as revenues.²⁷ Arkansas prohibits spread pricing, while Louisiana prohibits spread pricing unless a PBM provides a written notice at least biannually to policyholders indicating the aggregate spread pricing amounts charged by the PBM in that period.²⁸
- **Retroactive payment adjustments.** Three of the five states regulate PBMs' ability to retroactively reduce or deny payments to pharmacies. For example, Maine and Arkansas prohibit retroactive payment reductions except in cases of fraud or error.²⁹
- **Pharmacy reimbursement rates.** Three of the five states regulate PBMs' reimbursement of pharmacies. Arkansas and Louisiana prohibit pharmacy benefit managers from reimbursing a pharmacy not owned or affiliated with a PBM less for a pharmacy service, such as filling a prescription, than the PBM would reimburse a PBM-owned or affiliated pharmacy for the same pharmacy service.³⁰ Both states also permit pharmacies to decline to fill a prescription if the pharmacy benefit manager would pay less than the pharmacy acquisition cost.³¹ Maine requires PBMs to reimburse pharmacies at ingredient cost plus a dispensing fee, minus any enrollee cost-sharing.³²
- **Maximum allowable costs (MAC) lists.** Four states regulate how PBMs use or construct their MAC lists in some way. MAC lists specify the maximum amounts PBMs will reimburse pharmacies for generic

²⁶Ark. Code § 23-79-2503.

²⁷In addition, while Maine has not enacted legislation regulating spread pricing, Maine officials told us that their regulations require PBMs to remit the proceeds of spread pricing to the enrollee or issuer in the same manner as rebates. Officials in New York told us that health maintenance organizations are required to include in their contracts with PBMs a prohibition on spread pricing.

²⁸Ark. Code § 23-92-505(c); LA Rev. Stat. § 22:1867.

²⁹24-A M.R.S. § 4350(8)(D); Ark. Code § 23-92-506(c).

³⁰Ark. Code § 23-92-506(b)(4)(A); LA Rev. Stat. § 40:2870(A)(8).

³¹Ark. Code § 17-92-507(e); LA Rev. Stat. § 22:1860.3(B)(1).

³²24-A M.R.S. § 4350(8)(A).

drugs and branded drugs with generic competition. Maine requires PBMs to use the same MAC list for all pharmacies.³³ Louisiana requires PBMs to make available to pharmacies a comprehensive list of drugs subject to their MAC lists and the sources used to obtain drug price data.³⁴ Louisiana, Arkansas, Maine, and California have established criteria for drugs' inclusion on a MAC list.³⁵

Transparency. To increase the transparency of PBMs' operations, all five selected states require PBMs to be licensed by or registered with the state, or both, and to provide certain information, such as rebates and fees, to the state or to the health plans with which they contract.

- **Licensure and registration.** All five states require PBMs to obtain a license to operate or register with the state, or both. State licensing and registration requirements may either be separate from reporting requirements or linked to each other. For example, in California, PBMs are required to register with the Department of Managed Health Care and must provide quarterly reports to health plans regarding rebates, fees, and other payments.³⁶ In Louisiana, PBMs must submit an annual transparency report to the Louisiana Department of Insurance to maintain their license.³⁷
- **Transparency reporting.** Laws in the selected states vary in how often and to whom they require PBMs to submit data. Maine requires PBMs to annually disclose drug pricing data to the state.³⁸ Arkansas operates on a system in which the Insurance Commissioner initiates PBM audits as necessary and requires PBMs to comply upon request.³⁹ Louisiana requires PBMs to report to the Louisiana Department of Insurance aggregate rebates from manufacturers, the aggregate percentage of those rebates that PBMs retain, and

³³24-A M.R.S. § 4350(1).

³⁴LA Rev. Stat. § 22:1864(A)(4).

³⁵LA Rev. Stat. § 22:1864(A); Ark. Code § 17-92-507(b); CA Bus. & Prof. Code § 4440(d); 24-A M.R.S. § 4350(2).

³⁶CA Health & Safety Code § 1385.005; CA Bus. & Prof. Code § 4441(e).

³⁷LA Rev. Stat. § 22:1657.1(A).

³⁸22 M.R.S. § 8732.

³⁹Ark. Code § 23-92-505(b).

aggregate administrative fees received.⁴⁰ New York requires annual reporting by PBMs of rebates and other information to both the state and the health plans.⁴¹ California requires PBMs to report quarterly on rebates and other information to the health plans with which they contract upon those plans' request.⁴²

Networks and access. All five selected states enacted legislation to expand patient access to affordable drugs, such as the following.

- **Pharmacy networks.** Two of the five selected states have laws that regulate PBMs' pharmacy network design or prohibit discrimination against unaffiliated pharmacies.⁴³ Arkansas requires that the nearest in-person pharmacy in a PBM's network be within a reasonable distance from an enrollee's home.⁴⁴ Arkansas also restricts PBMs from imposing more stringent certification standards on pharmacies in its network than those imposed by the state board without review and approval by the insurance commissioner in coordination with the state board of pharmacy.⁴⁵ Louisiana prohibits PBMs from "steering" enrollees to pharmacies in which the PBM has an ownership interest, unless they provide a written disclosure and receive acknowledgement from enrollees.⁴⁶
- **Limits on enrollee co-pays.** Three of the five selected states limit enrollee co-pays charged by PBMs.⁴⁷ Maine requires PBMs to cap point-of-sale costs for enrollees at the least of three amounts: the enrollee's cost-sharing amount, the price of the drug without any drug benefits or discounts, or the total amount the pharmacy will be

⁴⁰LA Rev. Stat. § 22:1657.1.

⁴¹N.Y. Pub. Health Law § 280-a(2)(c); N.Y. Ins. Law § 2904

⁴²CA Bus. & Prof. Code § 4441(e).

⁴³In addition, laws in Maine and California regulate issuers' or health plans' pharmacy networks but do not apply directly to PBMs. Maine has also promulgated a regulation requiring PBMs to demonstrate that their pharmacy network will be adequate for patients.

⁴⁴Ark. Code §§ 23-92-505(a)(1), 23-92-509(b)(2)(B).

⁴⁵Ark. Code § 23-92-506(b)(3).

⁴⁶LA. Rev. Stat. § 40:2870(A)(5)(a).

⁴⁷In addition, California law requires health plans to cap costs for patients at the lesser of the patient's co-pay or the retail price of the drug; however, this law applies to health plans.

reimbursed.⁴⁸ New York prohibits PBMs from collecting co-pays from enrollees greater than the charges submitted by the pharmacy.⁴⁹ Arkansas prohibits charging an enrollee more for drugs than the amount retained by the pharmacy from all payment sources.⁵⁰

- **Price disclosure to enrollees.** The five states have taken action to ensure that pharmacies are not prohibited in their contracts from informing enrollees when a less costly alternative to paying for a prescription through their insurance is available.
- **Utilization management.** Only one state regulates PBMs' use of step therapy, in which patients must try a less expensive drug before the PBM will authorize use of a more expensive drug.⁵¹ Specifically, Louisiana prohibits PBMs from requiring step therapy if the prescribed drug is already on the health plan's formulary, the beneficiary previously tried the prescribed drug, and the provider submits a justification and supporting clinical documentation.⁵²

Table 1 below provides a summary of the laws the selected states have enacted to regulate PBMs.

⁴⁸24-A M.R.S. § 4349(4).

⁴⁹N.Y. Pub. Health Law § 280-a(5)(b).

⁵⁰Ark. Code § 4-88-1004.

⁵¹Arkansas regulates issuers' use of step therapy, but it does not directly regulate PBMs' use of step therapy.

⁵²LA. Rev. Stat. § 40:2870(A)(15).

Table 1: Selected State-Level Actions to Regulate Pharmacy Benefit Managers (PBMs) Serving Private, Employer-Sponsored Health Plans, as of November 2023

State action	Arkansas ^a	California ^b	Louisiana ^c	Maine ^d	New York ^e
Imposes a duty of care on PBMs, generally to health plans					
Fiduciary duty	n/a	n/a	n/a	✓	n/a
Good faith	n/a	✓	✓	n/a	✓
Drug pricing and pharmacy reimbursement					
Regulates PBMs' use of manufacturer rebates	✓	n/a	n/a	✓	n/a
Regulates PBMs' use of spread pricing ^f	✓	n/a	✓	n/a	n/a
Regulates PBMs' ability to retroactively adjust pharmacy payments	✓	n/a	✓	✓	n/a
Requires PBMs to reimburse pharmacies at minimum thresholds	✓	n/a	✓	✓	n/a
Regulates how PBMs use or construct Maximum Allowable Costs (MAC) lists	✓	✓	✓	✓	n/a
Allows pharmacies to refuse to fill prescriptions reimbursed below their acquisition costs	✓	n/a	✓	n/a	n/a
Transparency					
Requires PBMs to be licensed by or registered (or both) with the state	✓	✓	✓	✓	✓
Requires PBMs to provide certain information to the state or health plans, such as rebates, fees, and other payments	✓	✓	✓	✓	✓
Networks and access					
Regulates some element of PBMs' pharmacy network design	✓	n/a	✓	n/a	n/a
Limits on PBMs' enrollee co-pays	✓	n/a	n/a	✓	✓
Allows pharmacies to inform patients of lower prices for their prescription drugs	✓	✓	✓	✓	✓
Utilization management	n/a	n/a	✓	n/a	n/a

Legend: ✓ = State has enacted legislation, n/a = State has not enacted legislation.

Source: GAO analysis of state laws. | GAO-24-106898

Note: In addition to these laws that directly regulate PBMs, selected states may regulate the prescription drug benefits offered by health plans. To the extent health plans contract with PBMs to deliver such prescription drug benefits, PBMs may also be required to adhere to those requirements. However, laws regulating health plans' prescription drugs benefits are beyond the scope of this report.

^aArkansas officials told us that except for the MAC list provision, they do not enforce PBM laws against PBMs that only serve self-insured plans.

^bCalifornia officials told us their PBM laws do not apply to PBMs serving self-insured plans.

^cLouisiana officials told us their PBM laws do not specifically address self-insured plans.

^dMaine officials told us the only PBM laws that apply to PBMs serving self-insured plans are the licensing and reporting requirements.

^eNew York officials told us their PBM laws apply to all PBMs, regardless of the type of plan they serve.

^fSpread pricing is a practice in which PBMs reimburse pharmacies at one rate and charge plans a different rate, retaining any positive difference as revenues.

Stakeholders Expressed Mixed Views on Selected State Actions to Regulate PBMs

Stakeholders we interviewed expressed mixed views about the actions the five selected states have taken to regulate PBMs. Most stakeholders—mainly state regulators, pharmacy associations, and national advocacy organizations—supported state efforts to impose a duty of care on PBMs, while most health plan associations and the PBM trade association generally opposed the imposition of a duty of care on PBMs. Additionally, most stakeholders also supported other legislative efforts such as increased transparency requirements, regulating rebates, and other pricing and reimbursement laws as well as network access laws. However, most health plan associations and the PBM trade association generally opposed state actions regulating pricing and reimbursement and network access.

Stakeholder Views on a Duty of Care Requirement for PBMs

Most stakeholders we interviewed told us they believed a duty of care requirement was appropriate for PBMs although some stakeholders we interviewed disagreed. Regulators from three states, officials from four pharmacy associations, and officials from three national advocacy organization told us that a duty of care should be imposed on PBMs. However, officials from four health plan associations, officials from one health plan, and officials from the PBM trade association told us that they did not think a duty of care should be imposed.

Stakeholders expressed varied views on the applicability of, need for, and scope of, a fiduciary duty requirement for PBMs, as in the following examples.

- **Applicability.** Regulators from the one state (Maine) that successfully enacted a fiduciary duty law told us that they believed a fiduciary duty was applicable to PBMs because PBMs exercise significant management and discretion over prescription drug coverage.⁵³ However, officials from a PBM trade association told us that plan sponsors are the fiduciaries since they are the ones offering and designing the benefits; PBMs are simply carrying out their

⁵³A national advocacy organization representing large employers' health care interests similarly stated that a fiduciary duty was relevant to PBMs due to their management over prescription drug benefits.

instructions. They also said that PBMs do not manage plan assets, as a fiduciary would.

- **Need.** Regulators from three selected states, as well as officials from four pharmacy associations and three national advocacy organizations, indicated that a fiduciary duty was necessary to ensure PBMs act in good faith, while others disagreed.
 - Regulators from two states told us that fiduciary duty laws would help remedy concerns they have about certain PBM business practices, such as PBMs violating their contracts with pharmacies, not notifying pharmacies of reimbursement errors, and improperly recouping reimbursements from pharmacies. One pharmacy association stated that health plans generally had little interest in pushing PBMs to change practices that were harmful to patients, and a fiduciary duty would allow patients to take legal action against PBMs for engaging in bad faith. Officials from a national advocacy organization representing patients stated that a fiduciary duty would help ensure that any financial savings that PBMs achieve are passed on to the patients. Officials from this organization noted that additional vertical consolidation in the health care market, such as PBMs owning their own pharmacies, creates the need for a fiduciary duty.
 - However, officials from four health plan associations, one health plan, and a PBM trade association told us that they did not think a duty of care, including a fiduciary duty, needed to be imposed on PBMs. An official from a health plan association and one from the PBM trade association noted that good faith and fair dealing are standard contracting language and are generally already expected of PBMs; therefore, additional legislation is not necessary. An official from the PBM trade association also stated that imposing a fiduciary duty on PBMs could increase prescription drug costs due to the increased liability associated with such a duty.
 - Regulators from the four selected states that have not enacted a fiduciary duty requirement for PBMs said their states were unable to do so due to political opposition from the PBM trade association or perceived concerns about ERISA preemption.⁵⁴ Due to these concerns, regulators from two states and pharmacy association officials from two states noted that their respective states settled for what they referred to as “lesser” duty of care standards such

⁵⁴ERISA preemption restricts the extent to which states can regulate covered benefit plans, including self-insured health plans and the entities administering those plans, such as PBMs, to ensure uniform benefits administration across state lines.

as good faith and fair dealing contract requirements. One state removed the duty of care provision from proposed legislation entirely.

- **Scope.** Some stakeholders disagreed on the entities (e.g., health plan, enrollee, pharmacy) to which they believed the fiduciary duty should be owed.
 - One official from a national advocacy organization representing large employers' healthcare interests stated that the fiduciary duty should only be owed to the health plan since PBMs work on behalf of the health plan. Officials from one pharmacy association and two national advocacy organizations stated that a fiduciary duty should be owed by PBMs to pharmacists, health plans, and patients. Additionally, an official from a national advocacy organization representing pharmaceutical manufacturers stated that in the event of a conflict of interest, the fiduciary duty to the patient should be prioritized.
 - However, one health plan association official highlighted that imposing a fiduciary duty on PBMs could result in a conflict of interest between plans and patients. This official stated that if a PBM owed a fiduciary duty to both a health plan and its beneficiaries, PBMs could face a conflict between what is best for individual plan beneficiaries and managing costs for the overall plan. For example, an individual plan member may need an expensive, off-formulary drug, but this could increase costs for the entire health plan.

Stakeholder Views on PBM Laws Related to Pricing, Transparency, and Access

Most state regulators, pharmacy associations, and national advocacy organizations we interviewed supported state efforts to regulate PBM drug pricing and pharmacy reimbursement, increase transparency about PBM business practices, and increase access of independent and community pharmacies to PBM pharmacy networks. Most health plan associations and the PBM trade association we interviewed opposed state actions regulating pharmacy reimbursement and network design, but some health plan associations supported increasing transparency reporting of rebates and other data along the entire pharmaceutical supply chain. Table 2 below provides information on whether each of the stakeholder groups we met with were generally in favor of or generally opposed to actions taken to regulate PBM in the five selected states.

Table 2: Stakeholder Positions on Areas of Pharmacy Benefit Manager (PBM) Regulation

Generally in favor or opposed							
Area of regulation	State regulators	Pharmacy Associations	Health Plan Associations	Employer Advocacy Organization	Patient advocacy organization	PBM trade association	Drug manufacturer advocacy association
Drug pricing and pharmacy reimbursement	(n=5)	(n=5)	(n=5)	n/a	n/a	n/a	n/a
Rebates	Yes (3)	Yes (4)	—	Yes	Yes	—	Yes
Spread pricing prohibition ^a	Yes (3)	Yes (5)	No (3)	Yes	—	No	Yes
Retroactive payment adjustments	Yes (2)	Yes (3)	—	—	Yes	—	—
Regulation of pharmacy reimbursement	—	Yes (5)	No (1)	—	—	—	—
Maximum allowable costs	Yes (1)	Yes (2)	No (1)	—	—	—	—
Transparency	Yes (5)	Yes (4)	Yes (3)	Yes	Yes	Yes	Yes
Networks and access	Yes (3)	Yes (4)	No (4)	—	Yes	No	Yes

Legend: — = Stakeholders did not offer a position, n/a = Not applicable because only one such organization was interviewed.

Source: GAO interviews with selected stakeholders. | GAO-24-106898

Note: Information in the table is based on interviews and correspondence between June and November 2023. “Yes” indicates that most of the stakeholder(s) who responded were generally in favor, “No” indicates they were generally opposed, and “—” indicates the stakeholder did not offer a position.

^aSpread pricing is a practice in which PBMs reimburse pharmacies at one rate and charge plans a different rate, retaining any positive difference as revenues.

Within each of the broad areas of PBM regulation, stakeholders offered comments regarding specific topics. See table 3 for a summary of comments offered by the stakeholders we interviewed. More detailed comments are in appendix II.

Table 3: Examples of Comments Offered by Stakeholders Regarding Areas of State Pharmacy Benefit Manager (PBM) Regulation

Area of regulation and comments offered to GAO	Stakeholder type(s)
Drug pricing and pharmacy reimbursement	
Rebates	
Should apply to patients at point of sale	Drug manufacturer association
Should apply to health plans so all members can benefit from lower premiums	Health plan
Should be transparently reported	State regulator, pharmacy association, employer advocacy association, patient advocacy association, drug manufacturer association
Spread pricing prohibition^a	
Bans were necessary due to lack of transparency with spread pricing	Pharmacy association, employer advocacy association
Had contributed to rising prescription drug costs	State regulator, pharmacy association, employer advocacy association
Preferred pricing options under spread pricing	Health plan association, PBM trade association
Spread pricing offered more flexibility for health plans	Health plan association, PBM trade association
Retroactive payment adjustments (i.e., “clawbacks”)	
Bans had effectively eliminated clawbacks	Pharmacy association
Clawbacks were based on arbitrary benchmarks and caused pharmacies to lose money on claims	Pharmacy association
Regulation of pharmacy reimbursement	
State’s Medicaid flat fee per prescription payment that is above costs should be expanded to private plans	Pharmacy association
Allowing pharmacists to decline prescriptions if payment is below costs could restrict patient access	Health plan association
Maximum allowable costs (MAC)	
Has resulted in increased pharmacy reimbursement	Pharmacy association
Has allowed pharmacies to successfully challenge inadequate PBM reimbursement	Pharmacy association
MAC laws can lead to higher copayment for patients	Health plan association
Transparency	
PBM transparency and reporting laws can apply to all types of plans, including self-insured plans	State regulator
More detailed reporting of PBM data is required	State regulator

Area of regulation and comments offered to GAO	Stakeholder type(s)
Reporting should be required across the entire pharmaceutical supply chain, including drug manufacturers	State regulator, pharmacy association, health plan association, patient advocacy association, employer advocacy association, PBM trade association
Reporting laws can create administrative burdens and increased costs	Health plan association
Networks and Access	
Laws ensure that community pharmacies are not excluded from PBM networks if they are willing to accept PBM contract terms	Pharmacy association
Laws ensure that independent or community pharmacies are paid the same as PBM-owned or affiliated pharmacies	State regulators, pharmacy association
A variety of network and formulary options allow plans flexibility to select based on plans' cost needs	Health plan association
Network adequacy laws hinder PBMs ability to control costs and monitor pharmacy quality	Health plan association

Source: GAO interviews with selected stakeholders. | GAO-24-106898

Note: Information in the table is based on interviews and correspondence between June and November 2023.

^aSpread pricing is a practice in which PBMs reimburse pharmacies at one rate and charge plans a different rate, retaining any positive difference as revenues.

State Regulators Identified Lessons Such as Providing Broad State Regulatory Authority and Robust Enforcement Powers

The state regulators we interviewed described the lessons they learned about regulating PBMs based on their varied perspectives and experiences. In some cases, they commented on the factors that either contributed to, or hampered, effective regulation and enforcement at the state level. Other stakeholders shared concerns about states creating a patchwork of laws that undermine large employers' ability to operate their plans under consistent requirements across multiple states.

Importance of broad regulatory authority. Four of five state regulators stated that granting state agencies broad regulatory authority was more effective than specific statutory provisions to regulate PBMs.

Regulators in one state said that the state's legislature provided them with broader authority with respect to PBMs than insurance regulators in most states, and that this allows the department to actively address emerging concerns related to PBMs. Specifically, state regulators told us that their PBM oversight law allows the department of insurance to take regulatory action it deems necessary to enforce a range of requirements related to market conduct, including network adequacy, pharmacy contracts, pharmacy audits, pricing models, and consolidation and integration in the PBM industry. As a result, officials said the department does not have to rely on specific statutory provisions alone to exercise its authority. The officials said that using this regulatory flexibility rather than relying on

statutes has reduced loopholes and industry influence over policy and allowed them to address problematic conduct and issue guidance without having to go through the legislative process again.

Regulators in another state characterized their agency's regulatory authority as among the most comprehensive in the country, although this was not always the case. The state originally regulated PBMs as they do other third-party administrators. However, the regulators we spoke with said that legislation was not sufficient to address PBMs, so the state enacted new PBM-specific legislation. They stated that they now rely on a combination of statute and agency rulemaking to regulate PBMs. The requirements not spelled out in statute were further developed through regulation, they said.

Regulators in a third state said that an important lesson in retrospect was the need to expand their general supervisory authority to include not just oversight of health plans, but the third-party administrators, like PBMs, that serve the plans. They provided examples of areas in which they believe more regulation is needed but said that narrow authorizing legislation without broad rulemaking authority prevents them from taking action. For example, they said that the state's statutory prohibition on spread pricing was not effective because it provided an exception that the department said it is unable to address without broader regulatory authority.⁵⁵

Robust enforcement. Some state regulators indicated that without robust enforcement, state PBM laws may not be effective, a view echoed by some of the other stakeholders we interviewed.

Regulators from the five states noted that they rely on complaints as the primary mechanism to ensure PBM compliance with laws and, in some states, had taken actions such as audits to address complaints. Regulators from three states said they had designated departments to investigate complaints. Regulators from one of these states noted that, in addition to acting on complaints, they have the authority to promulgate regulations to ensure compliance, and the registration and licensure process allow them visibility into PBM practices. Regulators from another state said they had not taken any enforcement actions to date because

⁵⁵Specifically, the exception allows PBMs to utilize spread pricing in this state so long as they provide a biannual written notice to plan enrollees.

the requirements were so new that they had not yet created an enforcement structure.

Other stakeholders also noted factors that hampered or facilitated the state's ability to investigate complaints. A pharmacy association in one state claimed that the only way PBM laws can be enforced is if there is a sufficiently large volume of complaints that warrants a local district attorney or state Attorney General's time to investigate given their workload. The pharmacy association said that, in their state, pharmacists must hire an attorney to sue PBMs over violations of the laws, and this is often too expensive. On the other hand, a pharmacy association in another state noted that having a designated agency to which pharmacies can address their complaints was more effective than submitting complaints directly to the PBMs.

Regulators from two states said that two keys to strong enforcement are substantial penalties and sufficient resources. The regulators explained that if PBMs do not face large financial disincentives, they may see paying minor fees as a cost of doing business. For example, one state regulator said they had imposed a \$4,000 per day penalty for every day of late filing of a required report after PBMs were opting to pay the previous one-time late fee of \$500. Regarding resources, this state regulator noted that they had created a bureau to handle PBM oversight, with 30 full-time equivalent positions, including a team of examiners, and authority to contract with outside consultants. In contrast, regulators from another state said that with only 3.5 staff in their department, they are limited in their ability to conduct oversight.⁵⁶

Reducing ambiguous or fragmented authority. Regulators from two states identified ambiguous or fragmented authority over different aspects of PBM activities as factors that limited their authority to enforce PBM laws. Regulators from one state said that their department is charged with collecting high-level information from PBMs through the registration process, but that the state law does not give the department direct oversight authority over PBMs. Further, the regulators said they only have jurisdiction over enrollee-facing practices—such as requirements pertaining to drug formularies or the adequacy of pharmacy networks—

⁵⁶Two pharmacy associations stressed the need for enforcement, noting that PBMs may not comply with state requirements if there is no threat of consequences, while a health plan association identified the lack of compliance monitoring as an impediment to regulatory compliance.

but not over PBMs' dealings with pharmacies or health plans in their state.

Regulators from another state noted that oversight authority in their state is split among three different divisions depending on the PBM function—specifically, the Board of Pharmacy when PBMs perform the functions of a pharmacist, the Department of Insurance when they act as payers of claims, and the state Attorney General in all other cases. Moreover, regulators said that the Department of Insurance's authority falls within the state's insurance code which allows them to address reimbursement and payment issues. However, the regulators said duties related to managing pharmacy benefits fall under the state's public health and safety code, and the laws do not clearly specify which agencies are supposed to enforce these provisions. The national advocacy organization representing employers' interests further described an inconsistent patchwork of laws across states, with many plans operating across state lines and needing to navigate this patchwork.

Clarity and precision in requirements. Three state regulators commented on the need for clear requirements to minimize unintended exceptions that may lessen compliance. Specifically, the regulators expressed that in order for PBM laws to be most effective, regulators should (1) be very clear about the information that PBMs must provide and how to report the data, and (2) provide clear, functional definitions for important terms.⁵⁷ For example, according to regulators in two states, some PBMs avoided complying with rebate pass-through requirements by defining these payments as fees.

Regulators in a third state described another situation where terminology can affect PBM behavior. Specifically, the officials said that PBMs there insist that financial penalties be referred to as "warnings," rather than penalties, because, according to the officials, having a record of penalties imposed by state regulators can prevent PBMs from obtaining federal contracts. This is a concern for large PBMs that may bid for business under federal programs, they said.

Information on PBMs across different kinds of plans. Three state regulators expressed their desire to have more information on pharmacy

⁵⁷In addition to providing PBMs and health plans with better clarity regarding their states' requirements, one state regulator also commented on the importance of obtaining input from technical experts on the feasibility of PBMs' ability to report the proposed requirements.

benefit managers serving self-insured plans, similar to the transparency that fully insured plans must demonstrate in their states. Regulators in these three states described how concerns regarding ERISA preemption of state regulation of self-insured plans affected the enactment or enforcement of PBM laws in their states and resulted in less transparency for PBMs serving self-insured plans. For example, an ERISA preemption issue that regulators in one state said they contend with relates to situations in which PBMs serving fully insured plans lose revenue due to PBM regulations, like limits or prohibitions on certain fees. The regulators said that, in such situations, PBMs may seek to recover those funds from other types of health plans, including self-insured health plans. These state regulators believed that ERISA preemption prevents the state from knowing whether or to what extent this may be happening, they said. Regulators in another state similarly noted that their state's narrow authority prevents them from having insight into PBMs serving self-insured plans. Regulators in a third state said that they are unable to hold PBMs serving self-insured health plans to the higher standards applicable to fully insured health plans until it is clearer which areas of PBM regulation are federally preempted by ERISA.

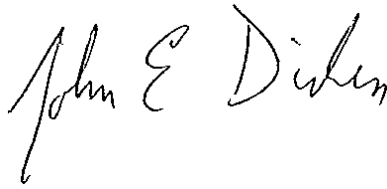
An official from the national advocacy organization representing employers' interests agreed with the need for greater transparency over pharmacy benefit managers and noted that some states have enacted laws that align with their PBM reform goals. However, the official also expressed concern about state regulation of PBMs that may conflict with one of the purposes of ERISA preemption—to allow large employers the ability to design uniform plans across multiple states. State regulation that varies widely across an employers' multiple locations also increases the employers' costs, according to the PBM trade association.

Agency Comments

The Department of Labor provided technical comments on a draft copy of this report, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Labor. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or DickenJ@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

A handwritten signature in black ink that reads "John E. Dicken". The signature is written in a cursive style with a large, stylized 'J' and 'D'.

John E. Dicken
Director, Health Care

Appendix I: Stakeholders Interviewed by GAO

To obtain the perspective of relevant stakeholders for this report, we interviewed regulators, health plan associations, and pharmacy associations from a selection of five states, as well as representatives from four national organizations.

State regulators. Arkansas Insurance Department, California Department of Managed Health Care, Louisiana Department of Insurance, Maine Bureau of Insurance, and New York Department of Financial Services.

Health plan associations. California Association of Health Plans, Louisiana Association of Health Plans, Maine Association of Health Plans, and New York Health Plan Association. In one state where there was no health plan association, we instead met with the state's largest insurer—Arkansas Blue Cross/Blue Shield—since the insurer covered 86 percent of individuals in the state in 2022.

State pharmacy associations. Arkansas Pharmacists Association, California Pharmacists Association, Louisiana Independent Pharmacies Association, Maine Pharmacy Association, and Pharmacists Society of the State of New York.

National organizations. Pharmacy Care Management Association (a trade association representing PBMs), the Business Group on Health, Patients for Affordable Drugs Now, and the Pharmaceutical Research and Manufacturers of America.

Appendix II: Stakeholders Views on Areas of State Pharmacy Benefit Manager (PBM) Regulation in Five Selected States

Most state regulators, pharmacy associations, and national advocacy organizations we interviewed in five selected states—Arkansas, California, Louisiana, Maine, and New York—supported state efforts to regulate PBMs. These efforts included laws that states enacted regarding drug pricing and pharmacy reimbursement, increased transparency about PBM business practices, and increased access by independent and community pharmacies to PBM pharmacy networks. Most health plan associations and the PBM trade association we interviewed opposed state actions regulating pharmacy reimbursement and network design, but some health plan associations supported increasing transparency along the entire pharmaceutical supply chain.

Stakeholder Views on PBM Laws Related to Drug Pricing and Pharmacy Reimbursement

All five state regulators, all five pharmacy associations, and three national advocacy organizations we interviewed supported state regulation of drug pricing and pharmacy reimbursements for PBMs. However, four health plan associations and the PBM trade association generally opposed state regulation of PBM drug pricing and pharmacy reimbursement practices.

- **Rebates.** Regulators from three states, four pharmacy associations, and three national advocacy associations supported policies regulating PBM's use of rebates but differed in the policies they favored.
 - **Application of the rebate.** One national advocacy association representing pharmaceutical manufacturers said that rebates should be applied at the point-of-sale to offset prescription drug costs at the counter. However, a health plan said that rebates should go to the health plan so that all members, not only those receiving prescription drugs, can benefit from rebates through lower premiums.
 - **Rebate transparency.** Two stakeholders also expressed support for rebate reporting requirements. A patient advocacy organization representative stated that rebate transparency would allow patients to see if drugs were on formularies because they are the most effective or because the PBM received greater rebates. Regulators from one state noted that despite having rebate reporting requirements in their state, the law has yet to have the desired impact of ensuring rebates are fully passed through to health plans and patients.
- **Spread pricing.** Regulators from three states as well as officials from all five pharmacy associations and a national advocacy organization representing large employers' healthcare interests supported spread pricing prohibitions due to the lack of transparency around spread

pricing and concerns that spread pricing increases prescription drug costs.¹ Most health plan associations and the PBM trade association opposed spread pricing prohibitions, noting that spread pricing provides plans with flexibility to manage prescription drug costs.

- **Effect on prescription drug costs.** A pharmacy association official stated that, prior to their state prohibiting spread pricing, the state insurance commissioner found that spread pricing was contributing to rising prescription drug costs. Regulators from one state noted that the state took action to prohibit spread pricing after the states' largest health plan elected a spread pricing option. The state regulators said that following pharmacist complaints, the state banned spread pricing and was able to successfully ensure that pharmacies were being paid what health plans paid for prescriptions. However, the state did not yet have information on whether or the extent to which prohibiting spread pricing has affected prescription drug costs. Officials from another pharmacy association stated that since PBMs in their state are only required to report the average spread, they are unable to see the extent to which spread pricing is occurring in their state.
- **Cost flexibility.** Three health plan associations, a non-profit health plan, and the PBM trade association supported allowing spread pricing as an option to provide flexibility for plans in managing their pharmacy benefits. Health plan officials said that spread pricing offered the health plan increased flexibility and stated that a spread pricing contract cost the health plan \$8 million less than a traditional pass-through contract. Additionally, officials from a health plan association also noted that many health plans in their state felt they had better pricing options prior to the implementation of the state ban on spread pricing.
- **Retroactive payment adjustments.** One state regulator and two pharmacy associations supported states prohibiting retroactive pharmacy payment reductions by PBMs. Pharmacy associations refer to these retroactive payment adjustments as "clawbacks." Officials from one of the pharmacy associations noted that their state's clawback ban had effectively eliminated retroactive reimbursement adjustments filed by PBMs. Officials from another pharmacy association located in a state where clawbacks were not prohibited told us that clawbacks were based on seemingly arbitrary benchmarks set by PBMs and caused pharmacies to lose money on claims.

¹Spread pricing is when PBMs reimburse pharmacies at one rate and charge health plans a different rate, retaining any positive difference as revenue.

- **Regulation of pharmacy reimbursement.** Officials from all five pharmacy associations supported existing laws that regulate pharmacy reimbursement and in some states advocated for additional legislation. However, officials from a health plan association opposed state efforts to regulate pharmacy reimbursement levels. Pharmacy association officials from two selected states said that their states' Medicaid program fixed pharmacy reimbursement that is equal to a flat fee per prescription plus the pharmacy's acquisition cost. The pharmacy association officials said that these laws ensure pharmacies serving Medicaid patients have a reliable revenue stream and do not lose money dispensing prescription drugs. Regulators from one of these states supported expanding these same requirements to commercial plans. One health plan association official stated that reimbursement and payment laws restrict patient access to medication in rural areas. For example, the same official noted that their state has a "decline to dispense" law that allows pharmacists to decline to fill a prescription if the PBM reimburses the pharmacy below the prescription's acquisition cost, which could affect patients' ability to access prescriptions in rural areas.
- **Maximum allowable costs (MAC).** Three stakeholders commented on state laws that regulate MAC lists. One pharmacy association official stated that they have seen increased pharmacy reimbursements in their state following the enactment of MAC list pricing legislation. This official noted a specific example where the pharmacy association was able to successfully challenge an inadequate reimbursement because of MAC list transparency requirements. Officials from a health plan association opposed regulating MAC lists because they said such laws can lead to higher co-pays for patients since the PBM is unable to adjust MAC list prices when needed.

Stakeholder Views on PBM Laws Related to Transparency

All stakeholder types we interviewed expressed support for PBM transparency requirements such as licensure, registration, and annual reporting on rebates and revenue sources. Regulators from all five states, officials from four pharmacy associations, officials from one health plan, and officials from three national advocacy organizations expressed support for PBM transparency requirements. Additionally, officials from three health plan associations supported transparency requirements that applied to all actors along the pharmaceutical supply chain such as manufacturers and wholesalers. However, some stakeholders we interviewed noted that some transparency laws do not go far enough and do not allow state regulatory agencies to collect information on such things as PBM revenue and expenses, rebate data, or spread pricing

information. Additionally, some stakeholders said that it is too soon to draw conclusions based on the collected data.

- **PBM transparency and reporting across all plan types.** Regulators from three states noted that their licensure, registration, and reporting requirements were generally applicable to PBMs serving all types of plans including Medicare Part D or self-insured plans. Regulators from one of these states said that they had the authority to inspect the record of any PBM, such as those contracting with self-insured or Part D plans, even if they cannot regulate the plans directly.
- **Shortcomings and additional reporting requirements.** Officials from a state regulator said that, while the additional insight from transparency requirements has allowed them to observe changes on an individual basis, it is too soon to draw conclusions on a systemwide basis. Officials from two pharmacy associations echoed this sentiment and noted that data is not yet available or too complex to be useful to consumers. Additionally, regulators from four states told us that additional information is needed to gain a better understanding of prescription drug cost drivers. For example, one state regulator said that despite having transparency laws, they have relatively limited information on PBM revenue sources and rebates. Similarly, officials with a patient advocacy organization stated that even with mandatory PBM reporting, other parts of the supply chain, and their effect on spending, will remain opaque.
- **Reporting challenges.** Three health plan associations expressed support for transparent reporting requirements along the entire pharmaceutical supply chain, including (for example) pharmaceutical manufacturers, wholesalers, and health plans. Two health plan associations warned against unreasonable reporting requirements due to the potential to increase costs and administrative burdens. Regulators from one state said that transparency laws should reflect the technological capabilities of PBMs to report the information requested by the state. One health plan association noted that transparency requirements alone may not address escalating prescription drug costs and instead create new administrative barriers without lowering costs.

Stakeholder Views on PBM Laws Related to Pharmacy Networks and Access

All state regulators, most pharmacy associations, and two national advocacy organizations we interviewed supported PBM laws regarding pharmacy networks, such as legislation addressing differences in reimbursement between PBM and non-PBM affiliated pharmacies as well as regulating utilization management practices, while four health plan associations we interviewed opposed limits on how PBMs create

pharmacy networks. Regulators from one state and officials from a pharmacy association supported “any willing provider” laws, which require PBMs to contract with any pharmacy willing to accept the terms of their contract, noting that these laws are an important consumer protection and allow pharmacies to gain access to PBM networks. Four health plan associations and the PBM trade association stated that network access laws hinder their ability to control costs and manage pharmacy quality.

- **Equal pharmacy reimbursement for independent and PBM-owned or affiliated pharmacies.** Regulators from one state and an official from one pharmacy association told us that prior to enacting patient access laws addressing pharmacy networks, they found independent and community pharmacies were being reimbursed at lower rates than PBM-affiliated pharmacies. Officials from a pharmacy association stated, and provided documentation to show, that patients were receiving mail telling them their pharmacy was out of network, only to receive additional correspondence that the letter was sent in error after they had already switched to an in-network pharmacy.
- **Utilization management and formulary development.** An official from the national advocacy organization representing patient interests stated that certain utilization management practices can prevent patients from accessing drugs prescribed by their physician. Another official, from the organization representing pharmaceutical manufacturers, noted that 79 percent of prescriptions go through three PBMs, and therefore it is difficult to access necessary drugs that are not on those PBM’s formularies.
- **Cost and quality control.** Four health plan associations and the PBM trade association stated that network access laws hinder PBMs ability to control costs and monitor pharmacy quality. Officials from two health plan associations stated that PBMs offer a variety of formulary and network options that health plans can select based on cost needs. A health plan association said that the network and formulary a health plan selects is based on network needs and the costs plans are willing to accept. Another health plan association official stated that they believed network access laws limit PBM’s ability to control costs. The PBM trade association noted that some any willing provider laws have been challenged in courts and that network adequacy laws can impact health plans’ margins.

Appendix III: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the contact named above, Iola D'Souza (Assistant Director), Perry Parsons (Analyst-in-Charge), Tim Planert, Emily Wilson Schwark, and Christopher Wolf made key contributions to this report. Michelle Duren, Joy Grossman, David Jones, Laurie Pachter, and Jennifer Whitworth also made important contributions.

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