

Highlights of GAO-24-106898, a report to congressional requesters

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 PBMrelated 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.

View GAO-24-106898. For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

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PRESCRIPTION DRUGS

Selected States' Regulation of Pharmacy Benefit Managers

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.