DIVISION OF RESEARCH
ISSUE BRIEF

Exploring Prescription Drug Affordability Review Boards (PDABs)

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Overview

In 2020, workers in 37 states spent 10% or more of their income on health insurance premiums and deductibles. This comes as health care costs continue to rise at a rapid rate. The forces driving health care costs are many, such as an increasingly aging population, high-cost development of medical technologies, and changes in lifestyle. Currently, prescription drug costs are a primal variable in driving up health care cost. Each year pharmaceutical manufacturers raise drug prices and in January 2024 more than 700 medications saw a 4.5% price increase. This causes many insured, and particularly uninsured populations, to bear more in out-of-pocket (OOP) spending, or worse, to not seek the care they need due to increasing costs. According to a survey conducted by the Kaiser Family Foundation, one in five adults do not fill a prescription due to the high costs, and others often resort to taking over-the-counter alternatives. In another study, the Centers for Disease Control and Prevention found that 9.2 million Americans did not take their medications as prescribed to save more money. The inability for patients to afford prescription drugs due to high costs can lead to further worsening their health conditions. Higher prescription costs also put a strain on state budgets. States contribute a substantial amount of their revenue to pay for their employee health benefits as well as for public health plans, such as Medicaid and Medicare. A hike in prescription costs leads to more health care expenditure which diverts funds away from other pressing issues states are addressing.

In addressing this issue, various measures have been implemented. At the federal level, the Biden Administration passed the Inflation Reduction Act which establishes several provisions aimed at addressing the sharp climb in drug prices. Within the state level, several states have passed transparency laws which require data reporting from manufacturers, pharmacy benefit managers (PBMs), and health plans. Other states have enacted state importation programs, which import drugs from other countries with approval from the U.S. Department of Health and Human Services. But at the forefront of addressing high prescription costs are Prescription Drug Affordability Review Boards (PDABs). PDABs aim to increase affordability for prescription drugs and to reduce government and commercial market spending. So far 9 states have passed legislation creating PDABs and 9 more states have pending legislation.

Advantages of Creating a PDAB

Increase Prescription Drug Affordability. Prescription drugs are the second highest out-of-pocket expenses (OOP) for patients (3.1%). High OOP costs continue to increase due to drug companies annually increasing the price of drugs. In June 2023 drug companies increased the list prices for 112 drugs above the annual inflation rate of 3%. A PDAB would increase drug affordability for patients through the various cost control mechanisms of rebate negotiations, through upper payment limits (UPL) on high-cost prescription drugs, or through issuing recommendations to the legislature.

Reduce Government and Commercial spending on Prescription Drugs. States contribute a substantial amount of their revenue toward paying insurance costs for employees (10% to 12%). Due to the rising costs of prescription drugs, many states are facing shortfalls in providing employee health benefits. Creating a PDAB may help lower drug costs which would lower state spending on health care.

Functions/Components of a PDAB

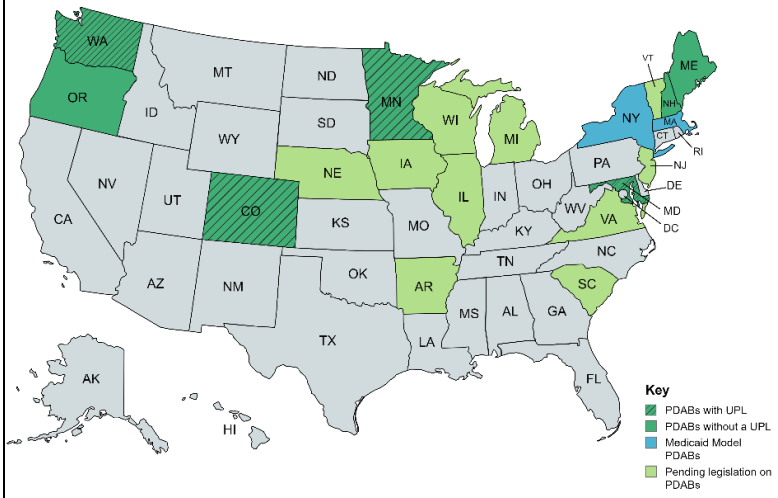
Structure. A majority of PDABs consist of five members appointed by the governor and confirmed by the senate. Board members are required to be subject matter experts in health policy, health care, economics, or clinical medicine, with other criteria as set by different states. Some PDABs are independent agencies, others are implemented within existing state agencies.

Funding. PDABs are funded through appropriating funds from the general fund if they are independent entities of the state. Other methods of funding include the collection of annual fees on manufacturers, PBMs, carriers, and wholesale distributers that sell prescription drugs.

Conducting Affordability Reviews. Affordability reviews help PDABs identify what drugs pose an affordability challenge to consumers. PDABs use certain "triggers" to determine what drugs to review such as price increases in the drug or drugs that meet certain thresholds.

Mechanisms of Cost Control. PDABs vary in their leverage power to lower drug costs. Some have authority to set UPL on high-cost prescription drugs. Other PDABs can only negotiate supplemental rebates on certain drugs or issue recommendations to the legislature on ways to reduce drug costs.

Comparing State's Activity on PDABs



Maryland was the first state to create a PDAB in 2019. Due to funding challenges, the Maryland board has yet to review or set UPL on any drug.

New York's Drug Utilization Review Board (DURB) has been able to negotiate agreements with drug manufacturers on supplemental rebates for two drugs (lumacaftor/ivacaftor, infliximab). In addition, the activities of the DURB produced an additional $24 million in savings.

Colorado's PDAB in 2024 declared injectable drug Enbrel, a drug treating autoimmune diseases, as unaffordable to patients in the state and is expected to announce further actions.

Considerations for Delaware Legislators Creating a PDAB

Ensuring Sustainable Funding. Delaware legislators creating a PDAB could consider following the structure of the boards in New York and Massachusetts. Primarily in the placement of these boards within existing state agencies. This ensures that funding is more stable as existing state agencies already have an established funding structure. Additionally, Delaware legislators could secure more funding for the board through the collection of annual fees on manufacturers, PBMs, carriers, and wholesale distributers that sell prescription drugs.

Mechanism of Cost Control Suitable for Delaware. States with PDABs that can set UPL have substantial and legally binding statutory authority to limit drug prices which can come with some success but with risks and limitations. Those include low political feasibility due to the substantial statutory authority to set UPL that would be granted to the PDAB. Another risk is a manufacturer withdrawing drug from sale in the state.

Obtaining Drug Price and Cost Information. To assess whether a drug poses an affordability challenge, PDABs must have access to relevant information to make that assessment. As such, Delaware legislators could consider granting authority to the PDAB to access proprietary information relating to drug prices from companies involved in the pharmaceutical supply chain. Delaware legislators could also consider entering into a memorandum of understanding with other states by requesting that drug manufacturers, PBMs, wholesale distributors voluntarily provide information relating to drug prices.

Legal Challenges. Thus far, PDABs have not faced any legal challenges. However, entities within the supply chain have voiced two legal concerns with the creation of a PDAB. First, they contest that PDABs with UPL setting power violate the Dormant Commerce Clause. Second, they argue that federal patent law preempts a PDAB from setting UPL.

- Delaware legislators could stipulate that the PDABs' UPL authority aims to target drugs actually being sold in the state, as opposed to drugs made available for sale, to prevent legal challenges to the legislation creating a PDAB.[1]

- To avoid legal challenges on the federal patent preemption, Delaware legislators could consider drafting the legislation creating the PDAB to include both patented and non-patented drugs to ensure that the law would not violate federal patent law.[2]

Additional Resources

- **Comparison of State Prescription Drug Affordability Review Initiatives.** Outlines each states' board and cites legislation creating PDABs. NASHP.

- **Prescription Drug Affordability Review Board Q&A**. Answers questions regarding PDABs functions and authority.(NASHP)

- **Model Legislation** for a PDAB. (NASHP)

- **Presentation on methods to use to identify drugs for affordability reviews**. Washington State Health Care Authority

[1] (*Association for Accessible Medicines v. Frosh*). The court referenced that Maryland's law applied to drugs "made available for sale" rather than drugs actually being sold in Maryland.

[2] In *Biotechnology Industry Organization v. District of Columbia*, the U.S. Court of Appeals for the federal Circuit struck down a Washington, DC law that made it unlawful, "for any drug manufacturer or licensee thereof…to sell or supply for sale…for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price."[2] The Federal Circuit argued that the law focused primarily on patented drugs and, "limit[ed] the full exercise of the exclusionary power that derives from a patent."