DIVISION OF RESEARCH

RESEARCH REPORT

Exploring Prescription Drug Affordability Review Boards (PDAB)

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OBJECTIVE

This report addresses the rising costs of prescription drugs by outlining national and state level trends in the health care industry. In addition, this report explores a policy solution to mitigating the rising costs of prescription drugs by establishing a Prescription Drug Affordability Board (PDAB). Furthermore, this report highlights the policy considerations for establishing PDABs in Delaware by addressing legal challenges to PDABs, determining the mechanism for cost control suitable for Delaware, obtaining drug price and cost information to assist in the PDABs analytical work, and ensuring a source of sustainable funding.

INTRODUCTION

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 one of the main variables driving up health care costs. 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 expenditures 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 Board (PDAB). 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.

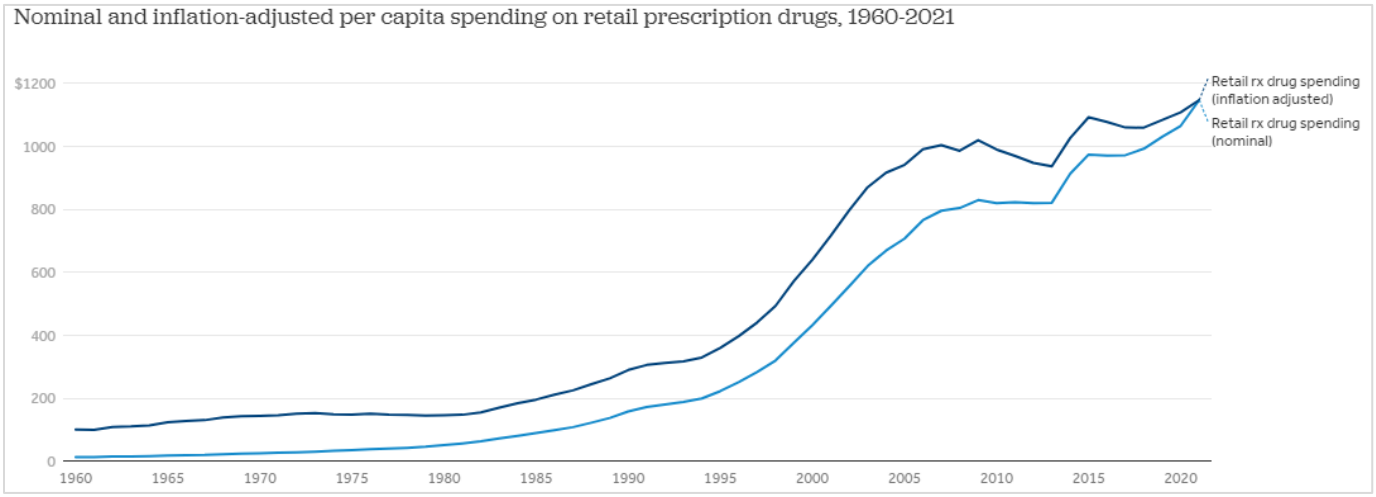
NATIONAL TRENDS

The U.S. is the largest spender on health care when compared to other developed countries. On average, the U.S. spends $12,555 per person, which is over $4,000 more than any other high-income country. In countries with similar GDP to the U.S., they spend about half what the U.S. spends per person. The rate of health care expenditure in the U.S. has more than tripled from 1990 ($718.7 billion) to 2021 ($4.255 billion) and has increased by 6.2 in percent of GDP from 1990 (12.1%) to 2021 (18.3%).

More than 50% of U.S. expenditures on health care falls under three categories, hospital care (31.1%), physician services (14.9%), and prescription drugs (8.9%). All three categories have seen an increase in spending; however, a major increase was seen in retail prescription drugs. U.S. spending on retail prescription drugs has increased rapidly over the past three

decades (figure 1). The U.S. Center for Medicare and Medicaid Services (CMS) highlights that retail prescription drugs spending increased 8.4% to $405.9 billion in 2022, which is a faster rate than in 2021 when spending increased by 6.8%.

Figure 1. *(Source : KFF analysis of National Health Expenditures Accounts)*



Prescription drugs are also the second highest out-of-pocket expenses for patients (3.1%) with physician and clinical services accounting for 8.8% of out-of-pocket expenses. To further add to increasing health care costs, drug companies increase drug prices annually. In June 2023, drug companies increased the list prices for 112 drugs above the annual inflation rate of 3%, some drugs saw an increase of more than 8%. According to the Office of the Assistant Secretary for Planning and Evaluation (ASPE), between January 2022 and January 2023, more than 4,200 drug products had price increases, with the average drug price increase of the period coming to 15.2%.

NATIONAL EFFORTS TO REDUCE DRUG PRESCRIPTION COSTS

In addressing high prescription costs, the Inflation Reduction Act (IRA) was passed in August 2022 which contains several provisions aimed at lowering prescription drug costs and reducing drug spending by the federal government. The IRA aims to negotiate directly with drug companies to determine the prices that Medicare will pay for certain high-cost drugs covered under Medicare Part D starting in 2026 and Medicare Part B starting in 2028. In addition, the IRA caps out-of-pocket drug spending to $2,000 for Medicare beneficiaries, however, this will not apply until 2025. According to CMS projection estimates, the IRA is likely to lower OOP spending on prescription drugs for 2024 for Medicare beneficiaries (figure 2).

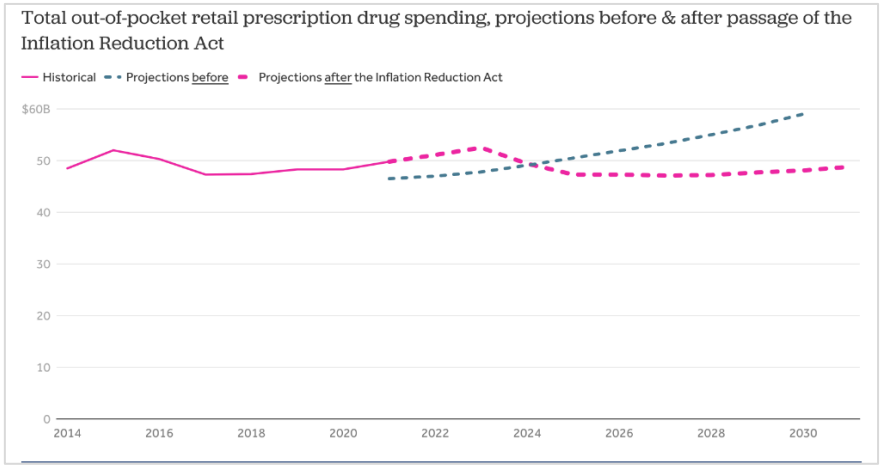


Figure 2 *(Source: KFF analysis of National Health Expenditures Accounts (NHEA))*

STATE TRENDS

State	Total Health Care Expenditure[1] (Year 2020) (in millions)	Per Capita[2] (Year 2020)
US	$3,357,832	$10,191
Delaware	$12,729(CMS) $9,131 (DHSS)	$12,899(CMS) $9,099 (DHSS)
Maryland	$65,641	$10,839
Pennsylvania	$148,327	$11,603
New Jersey	$105,416	$11,868
New York	$270,847	$14,007

Table 1 (Source: Center for Medicare and Medicaid Services (CMS))

In 2020, states and local governments spent $345 billion on health and hospitals or 10% of direct general spending. The largest expenditure category for many states is Medicaid (30%) which is steadily increasing each year. States also 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. This poses many problems for states and prevents states from addressing other pressing issues.

DELAWARE HEALTH CARE SPENDING

The state with the highest per capita spending on health care is New York followed by Delaware. Delaware's per capita expenditure is more than the national average by a 23% difference. However, it is important to note that the Delaware Department of Health and Social Services (DHSS) reports a different per capita spending. According to DHSS Benchmark Trend Report, Delaware's per capita health spending in 2021 was $9,099, which is less than the national per capita reported by CMS. DHSS also reported that Delaware's total health care expenditures has increased over the years (2019 – 2021). From 2020 ($8.1 billion) to 2021 ($9.1 billion), Delaware's total health care expenditures saw an increase of 11.2%. Similarly, Delaware's total expenditures on retail prescription drugs saw an annual growth of 10.6% from 1980 to 2020. Based on CMS data, Delaware saw the highest annual growth increase in total expenditures on retail prescription drugs from 1980-2020 compared to the four neighboring states (Maryland (8.5%), Pennsylvania (8.4%), New Jersey (8.9%), New York (9.3%)).

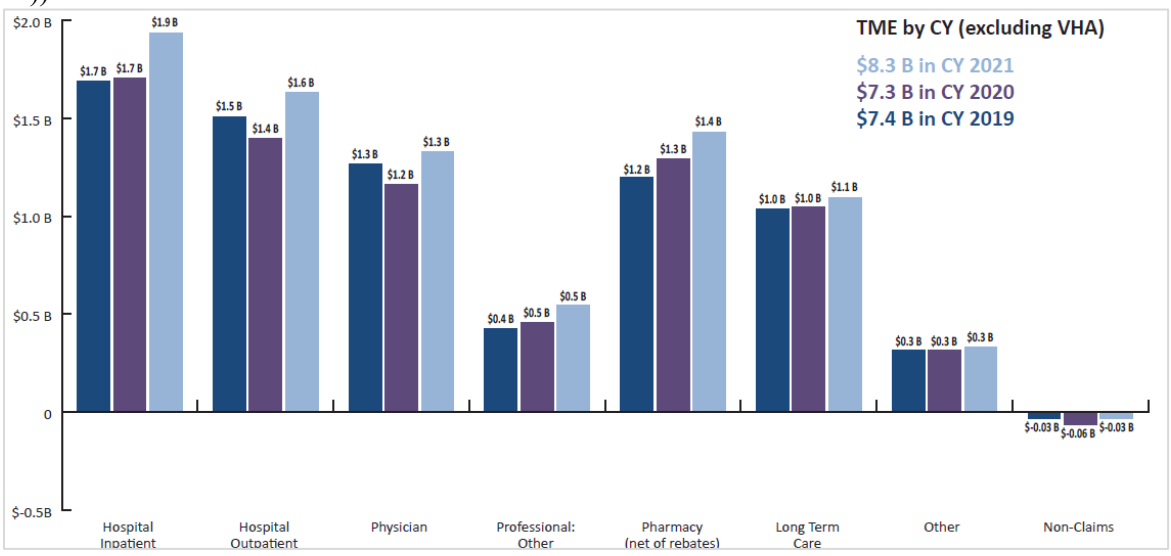


***Table 2**. State Level Total Medical Expenses by Service Category (Source: DHSS Benchmark Trend Report)*

[1] **Total health expenditure**: spending for all privately and publicly funded personal health care services and products (hospital care, physician services, nursing home care, prescription drugs, hospital spending). What is not included in the definition of total health care expenditure are costs such as insurance program administration, research, and construction expenses.

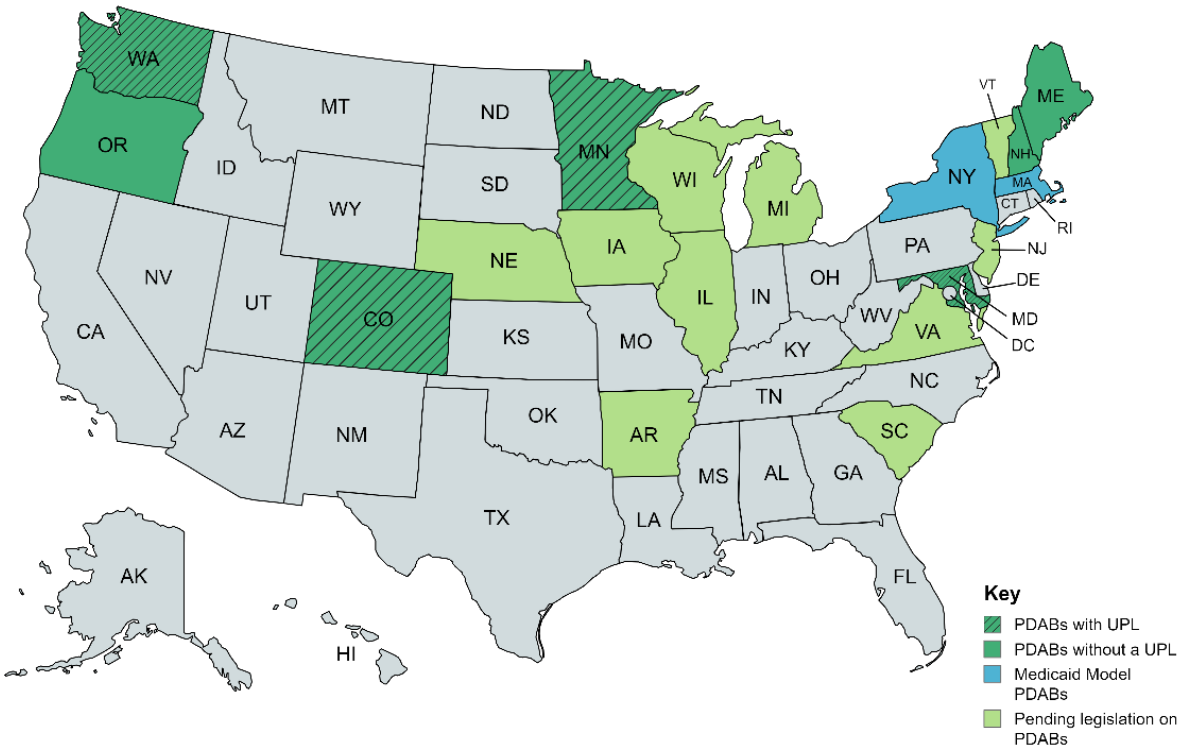
[2] **Health spending per capita**: includes spending for all privately and publicly funded personal health care services and products (hospital care, physician services, nursing home care, prescription drugs, hospital spending) by state of residence.

PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD

Maryland was the first state to establish a PDAB in 2019 using the National Academy for State Health Policy's (NASHP) model legislation. The 12-page model legislation states that the purpose of a PDAB is to increase access to affordable prescription drugs through various measures such as conducting an affordability review by identifying which drugs pose an affordability challenge, setting upper payment limits (UPL), and through providing recommendations and information to the state legislature regarding lowering prescription drug costs. As of 2024, 8 states have followed Maryland's lead in implementing PDAB with 9 states having pending legislation. A majority of PDABs consist of five members appointed by the governor and confirmed by the senate. Board members in PDABs are required to be subject matter experts in health policy, health care, economics, or clinical medicine, with other criteria as set by different states. To access more information on legislation passed in states with PDABs or track legislation introduced on this subject, the NASHP offers a database that tracks all legislation relating to PDABs and offers a comparative list of the PDABs.

FUNCTIONS

While 9 states have boards called PDAB, it's important to note that the boards differ in scope and authority. For example, some of the states classify their PDABs as an independent unit of their state government (Maryland, Maine, New Hampshire), while others establish their PDABs within state agencies (Oregon, Massachusetts, New York). In a majority of states with PDABs, only certain plans would be impacted by the decisions of PDABs. Certain PDABs only apply to public plan enrollees (Maine, New Hampshire, Maryland), while other PDABs address only Medicaid enrollees such as the PDABs in New York, and Massachusetts. Other PDABs go even further to include all consumers in the state (Minnesota, Colorado, Washington). The populations impacted by the regulations and decision of the PDAB's plays an important role in determining the amount of savings that would be incurred. Below is a list of various tools that PDABs across states use to lower prescription drug costs. Some states with PDABs have one or more combinations of these tools to lower prescription drug spending.



CONDUCTING AFFORDABILITY REVIEWS

A majority of PDABs have authority to conduct drug affordability reviews. Affordability reviews help PDABs identify what drugs pose an affordability challenge to consumers. The NASHP model legislation establishes some of the criteria that states can use to determine which drugs are up for review. For example, one of the criteria in the model legislation is to consider drugs that meet certain price thresholds. In Colorado's PDAB, brand-name drugs and biologics with a launch wholesale acquisition cost (WAC) of $30,000 or more per course of treatment is one criterion. In Washington's PDAB, the criterion is different and applies to brand-name drugs and biologics with a WAC of $60,000 or more per year or course of treatment. Another criterion that PDABs use to determine which drugs need to be reviewed is based on the price increases of WAC of a drug. Under New York's PDAB, a brand-name drug or biologic with a WAC increase of $3,000 or more in any 12-month period is due for review. These criterions act as triggers to help PDABs identify which high-cost drugs should be reviewed in order to determine if they create an affordability challenge.

Since the establishment of PDAB in Colorado, over 600 drugs were reviewed by the board and five are being closely reviewed to assess their affordability using the criterions established by the board. The Maryland PDAB has just begun operations due to challenges in securing funding and is developing action plans.

Thresholds Established in Maryland and New York

State	Brand-name Drugs	Price Increase	Biosimilar Drugs	Generic Drugs	Other
Maryland	Launch WAC of $30,000 or more in a year	Brand-name drugs or biologics with a WAC increase of 10% or more during the preceding 12 months	Launch WAC that is not at least more than 15% lower than the referenced biologic	WAC of $100 or more for a 30-day supply or course of treatment or that increased by 200% in preceding year	N/A
New York	Including biologic, with a launch WAC of $30,000 or more per year or course of treatment	Brand-name drug or biologic with a WAC increase of $3,000 or more in any 12-month period	Launch price that is not at least 15% lower than the referenced biologic	WAC of $100 or more for a 30-day supply or course of treatment	Drugs purchased by Medicaid that are contributing to spending that will exceed the State's Medicaid drug cap

SETTING UPPER-PAYMENT-LIMITS

According to NASHP's definition, a upper payment limit (UPL) is the maximum reimbursement rate above which purchasers throughout the state may not pay for prescription drugs. This does not mean that a PDAB is setting a price by setting a UPL – which is against federal law – rather, it creates a maximum on what a payer in the supply chain can pay for a drug. By setting a UPL, payers such as commercial insurers, health care providers, pharmacies, consumers, and the state, would pay below the UPL established by the PDAB for the high-cost prescription drug.

Not all states with PDABs have authority to establish UPL on high-cost prescription drugs. Currently, only Colorado, Maryland, Minnesota, and Washington have authority to set a UPL. Colorado's PDAB has authority to set UPL to all payers in the state for up to 12 high-cost drugs during the first three years of implementation unless determined otherwise by the board. Maryland's board is only authorized to set UPL for state and local government payers and requires approval of the states' legislature to have the UPL apply to the drug. Setting a UPL requires a consideration of various factors. In Colorado's PDAB, the board's UPL methodology considers a variety of pricing or cost information before setting a UPL. These include considering patient OOP costs, whether the drug is on the drug shortage list, the impacts on the elderly and disabled, and stakeholder inputs. Similarly, in Washington's PDAB, the board is authorized to set UPL on 12 high-cost prescription drugs and must consider similar price or cost information. Minnesota's PDAB was recently established and is

set to begin operations. Minnesota's PDAB is authorized to set UPL in reference to the federally negotiated Medicare maximum fair price (which was established by the IRA) for any drug with a Medicare maximum fair price.

REBATE NEGOTIATIONS & DETERMINING SPENDING TARGETS

The PDABs in Maine and New Hampshire utilize a different process for selecting drugs to be reviewed as well as different mechanisms of cost controls. Both Maine and New Hampshire identify universal and drug-specific spending targets that pose an affordability challenge to enrollees in a public plan. The PDABs in Maine and New Hampshire act to only recommend or advise non-Medicaid, state-financed public payers on how to meet drug-spending targets. If payers do not meet the spending targets, the PDABs in Maine and New Hampshire can negotiate rebates for high-cost drugs, however, the boards do not have authority to require public payers to take any actions on reaching the spending targets.

In New York and Massachusetts, their boards have authority to negotiate supplemental drug rebates paid by state Medicaid programs. Under the board in Massachusetts, a drug is identified as a high-cost drug as those with a post-rebate price of more than $25,000 per person annually. For New York's Drug Utilization Review Board (DURB), the board does not select the drugs it reviews, instead the New York Department of Health makes the determination (if the Medicaid prescription-drug spending cap is exceeded) of the high-cost drugs to be reviewed.

EFFICACY OF PDAB

To date, there is limited information regarding the effectiveness of PDABs in reducing prescription drug costs. Many of the boards were established in the beginning of the COVID-19 pandemic which resulted in a diversion of funds away from the boards. This caused many boards to postpone operations until funding is secured. This makes it difficult to assess whether PDABs lower prescription drug costs and produce savings for the state. However, the boards in New York and Colorado have made some progress towards lowering high-cost prescription drugs. Since the creation of New York's DURB in 2017, the 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. However, those savings are minimal when considering New York spent $1.3 billion on prescription drugs in that same period. More recently, in 2024, Colorado's PDAB declared injectable drug Enbrel, a drug treating autoimmune diseases, as unaffordable to patients in the state and is expected to announce the UPL in the coming month.[3]

CONSIDERATIONS

MECHANISM OF COST CONTROL SUITABLE FOR DELAWARE

If adopting a PDAB in Delaware, legislators should consider the mechanisms of cost control that would be best suited for a PDAB in Delaware. As highlighted in this report, states have taken various approaches to the type of cost control mechanism given to PDABs. These play critical roles in ensuring that the PDABs have substantial leverage to lower drug costs. 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 also with the risks and limitations highlighted below:[4]

[3] It is also important to note that Colorado's PDAB also recently declared a cystic fibrosis drug which costs $200,000 a year as affordable to patients due to assistance programs that cover most of patients OOP costs.

[4] In a report published by Maryland's PDARB, when comparing the maximum fair price model under the IRA which the CBO estimates a 3.1% saving, the PDAB in Maryland applied the same savings rate to the net spending for prescription drugs for state employees ($270.5 million) and found that the state would save $8.3 million.

- **Manufacturer withdraws drug from sale**[5]. One risk is that drug manufacturers can evade the UPLs set by the PDABs by removing the drug from sale in the state with a UPL. However, the NASHP argues that this is unlikely to occur due to the major shifts in the supply chain drug manufacturers would have to make to prevent drugs from reaching a state with a UPL. NASHP also argues that this would disadvantage drug manufacturers leaving the state due to the number of drugs in the market that are similar in treatment effects.
- **Substantial statutory authority leads to lower political feasibility**. Another risk with giving a PDAB substantial statutory authority to set UPLs is the ability to pass the legislation that would create PDAB. The PDAB in Maryland faced political controversy with one factor being due to the substantial statutory power delegated to the board. Similarly, in the initial draft of the legislation creating the Maine PDAB, provisions were made to grant UPL setting authority, however amendments were passed to remove those provisions.

Another mechanism of cost control for Delaware legislators to consider is the leverage power of New York's DURB. If a manufacturer refuses to meet the recommended target rebate of the DURB, the board can either require a prior authorization requirement for the drug for Medicare beneficiaries or remove the drug from the formulary. And, as mentioned earlier, the work of New York's DURB has been able to negotiate additional rebates that realized $24 million in savings. One limitation of this model is that it only applies to Medicaid programs, which can limit the amount of savings that the state can attain if the board expanded its scope.

Ensuring Substantiable Funding

Funding is critical to achieving the optimal effectiveness of the PDAB. As stated before, the variable that hindered many of the PDABs ability to begin operation, is funding challenges. Delaware legislators 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 a funding structure. To contrast, if a PDAB was to be independently run – like the PDAB in Maryland – a new funding structure would have to be implemented which will create appropriation challenges.[6] 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.

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. This would require the implementation of drug price transparency laws which would help the PDAB and Delaware legislators to understand and access information related to drug prices and costs enabling informed decision making. Thirteen states have implemented drug transparency laws which require supply chain entities to provide information on drug prices. This tool would be used in tandem with PDABs which would aid PDABs instead of having the PDABs rely on only public information relating to drug costs. Currently, the boards in New York, Massachusetts, and Washington are the only boards that have authority to compel drug manufacturers to provide information related to their drugs and other proprietary information. These boards

[5] States with PDABs have established enforcement mechanism for manufacturers that withdraw their drug from sale in the state due to UPL settings. In Washington for example, a manufacturer who withdraws a drug from sale in the state is prohibited from re-entry for 3 years unless they agree to a UPL. Other states require manufacturers to file a notice and failure to do so within a time-period results in a fine.

[6] In Maryland, the Governor halted operations for the Maryland PDAB by vetoing bill that would have secured funding for the board.

can also impose a penalty if manufacturers refuse to provide the required information requested by the boards.[7] In other states like Maryland, Colorado, Maine, and Oregon, the boards can enter into a memorandum of understanding with other states by requesting that drug manufacturers, PBMs, and wholesale distributors voluntarily provide information relating to drug prices. If no information is provided from any in the supply chain, the boards in Maryland, Colorado, Maine, and Oregon may not consider their refusal in the determination of whether the drug has created an affordability challenge. The NASHP provides a database tracking how other states have implemented drug transparency laws and can be found here as a resource for Delaware legislators to consider.

LEGAL CHALLENGES

Thus far, PDABs have not faced any legal challenges. However, it's important that Delaware legislators be aware of the legal challenges that could potentially arise following the creation of a PDAB in Delaware. Entities within the supply chain have voiced two legal concerns with the creation of a PDAB. These legal challenges are in particular to the power of setting UPL that some PDABs have.

Dormant Commerce Clause

The first legal challenge brought by supply chain entities, is that a PDAB with power to set UPL violates the dormant commerce clause. Supply chain entities contest that setting UPL would burden out-of-state competitors for the benefit of interstate economic interest. This argument, however, does not take into consideration that a PDAB is only setting a UPL on payers in the state and does not affect a manufacturers' list price for a drug.[8] In creating a PDAB, 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.

Federal Patent Preemption

The second legal challenge raised by entities in the supply chain is that federal patent law preempts a PDAB from setting UPL. 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."[9] 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."[10] Thus, 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. In addition, it's important to note that a PDABs authority to set UPL is not dictating the price a manufacture is able to charge, rather the UPL is only limiting what a payer is willing to pay. That is, negotiations between payers, such as pharmacies and wholesale distributers, would be no more than the UPL established by the PDAB.

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[7] Washington's PDAB imposes a $100,000 fine for failure to comply with information requested. Massachusetts imposes a $500,000 penalty for failing to submit a truthful and complete standard reporting form.

[8] Maryland enacted HB 631, which prohibited drug manufacturers from price gauging, "in the sale of an essential off-patent or generic drug." The U.S. 4th Circuit Court of Appeals struck down the bill because it violated the DCC on the grounds that, "it directly regulates transactions that take place outside Maryland." (*Association for Accessible Medicines v. Frosh*). The court referenced that the Maryland's law applied to drugs "made available for sale" rather than drugs actually being sold in Maryland.

[9] D.C. Code § 28-4553

[10] *Biotechnology Industry Organization*, 496 F.3d Id. 1374