REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 8-A-25

Subject: Prescription Drug Affordability Boards

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Policy D-110.984 was adopted at the 2024 Annual Meeting and asks our American Medical Association (AMA) to study how upper payment limits (UPLs) established as a part of prescription drug affordability boards (PDABs) impact physician reimbursement and patient access to medications. The following informational report discusses the background of PDABs, the current state of these boards, potential impacts on patients and physicians, and existing AMA policy on the topic.

BACKGROUND

Drug prices in the United States (U.S.) make up nine to ten percent of total medical spending each year, or over $700 billion annually.[1] Research demonstrates that over the last 65 years, the prices of prescription medications have increased faster than both inflation and non-prescription medications.[2] This is due largely to high-priced branded drugs, which make up about 80 percent of U.S. drug spending.[1] American spending is also significantly higher than other comparable nations, with estimates of spending on prescription drugs over 200 percent higher per capita. This higher level of spending does not appear to result from American patients purchasing a higher quantity of medication, as the same study found that U.S. consumers purchased 12 percent fewer days of medications than patients in the other similar nations.[2] Rather, the high drug costs in the U.S. are a result of an incredibly complex, and largely opaque, system. While not all-encompassing, experts specify that the higher spending comes from a combination of higher transaction prices, selection of more expensive medications, monopoly pricing, patent extensions/gaming, and influential rebates.[1,2,3]

In an attempt to combat high drug prices and patient out-of-pocket (OOP) costs for medications, some states have begun to pass legislation to implement PDABs.[4,5] The first PDAB was established in Maryland in 2019 and in recent years more states have enacted legislation creating PDABs.[5] However, few states have actually begun to implement the work that is outlined in legislation, making the impact of these PDABs difficult to assess. Generally, PDABs are designed to both evaluate the jurisdiction's (typically a state's) spending on prescription drugs and to establish methods for lowering this spending. While there is a wide variety in the makeup, scope, and power of these boards, most focus on a specific set of prescription medications and release reports evaluating the state's spending and recommendations to increase affordability.[6] PDABs are often made up of health care providers, advocates, payer representatives, and patients/patient group representatives. Members are typically selected via an application process or by gubernatorial/congressional appointment.[6,7]

The majority of the states that have enacted PDABs utilized the National Academy for State Health Policy's (NASHP) model legislation, originally released in 2017 and updated in 2022, which includes references to federal legislation on drug pricing.[8] This model legislation is designed to

give states the authority to establish a framework that defines which medications are "unaffordable." The NASHP model bill includes PDAB authority to define upper payment limits (UPLs) for medications that are designated as "unaffordable."[8] UPLs are designed to set a maximum price for a specific drug based on its cost-effectiveness and affordability.[7] UPLs are intended to prevent price gouging and ensure that patients have access to essential medications. While state PDABs do not automatically have authority to establish UPLs, some states have chosen to include this authority.[7,8]

STATE PDABs

As of March 2025, 11 states (CO, ME, MD, MA, MN, NH, NJ, NY, OH, OR, and WA), have enacted legislation and some have begun to implement PDABs.[9] Details of each of the existing state PDABs can be found in Appendix A. Some states have limited the impact of PDABs to only public plan enrollees, others have incorporated the boards as a part of Medicaid plans only, while other states have indicated the intent for expansion to all enrollees, regardless of payer type. While many states have chosen not to include UPLs, four states, Colorado, Maryland Minnesota, and Washington, have included authority to establish UPLs.[9,10]

Each state has outlined different methods for selecting board members and medications, funding the work, and the reach of authority. Some states, like New York and Massachusetts have incorporated PDAB authorities into existing governmental organizations, NY Medicaid and MA Health and Human Services, respectively.[11,12] As a result, no additional funding or employees were allocated to those states' boards. However, other states have made significant investments in establishing a PDAB. For example, Oregon, Washington, and New Jersey have allocated at least $1.5 million each for the startup of the boards.[13,14,15] Funding origins are also diverse with some states, like Colorado, listing it as a state budget line while others have alternative funding sources.[16] Specifically, states like Oregon and Maryland plan to generate future funding via fees on drug manufactures, insurance carriers, wholesale distributors, and/or Pharmacy Benefit Managers (PBMs).[13,17]

States also vary in the makeup of boards and the impacted population(s). In addition to the employees that some states have hired (or plan to hire) to run the PDAB, states have chosen various methods to select board members. Most states utilize/plan to utilize a combination of appointments from congressional leaders and/or the governor. However, the makeup of expertise on the board varies from state to state.[6,8] Many states encourage or require that patients or patient advocates be a part of the board, while other states, like Colorado and Washington, require a certain level of drug pricing policy or clinical expertise for a certain subset of board members.[14,16] Further, states vary in the length of time board members can serve and if they must be confirmed by the state legislature. Additionally, states vary greatly in the populations that will be impacted by the outcome of PDAB decisions. Many states, like Maine, Maryland, and New Hampshire, have chosen to focus only on public plan beneficiaries.[17,18,19] However, other states, like Colorado, Minnesota, and Washington, have chosen to focus on all consumers with minor exceptions for plans preempted by the Employee Retirement Income Security Act that chose to opt out.[14,16,20]

In addition to the differences in the structure and authority of PDABs, states differ in which drugs are eligible to be covered. A few states have relatively open criteria while others have more stringent requirements. States like New Hampshire and Maine focus on any prescription medications that are purchased by public payers and may cause "affordability challenges."[18,19] However, the majority of states have more strict criteria typically centering around drugs with high wholesale acquisition cost (WAC) launch prices, have substantial percentage WAC increases, those with a certain WAC price, and/or generics that are not a specified percentage less expensive than

the reference medication. For example, in Maryland for a drug to be considered by the PDAB it must meet the following criteria:

- if the medication is brand name and has a WAC of $30,000+ or a $3,000+ price increase in 12 months; or
- if the medication is a biosimilar and has a WAC that is less than 15 percent lower than the reference medication; or
- if the medication is generic and has a WAC of more than $100 for a 30-day prescription or an increase in WAC over 200 percent.[17]

While the details vary by state, those with more specific criteria tend to be comparable to the aforementioned requirements in Maryland. However, Oregon has unique criteria in that the legislation outlines the selection of 10 drugs to be reviewed each calendar year. One of the selected drugs must be an insulin product and the other nine are selected from the state's Prescription Drug Price Transparency Program, excluding any medication designed to treat a Food and Drug Administration (FDA) designated rate disease or condition.[13] Additionally, some states, like Ohio, have chosen to not focus on specific drugs but, rather, to focus on strategies to reduce overall drug spending, increase transparency, and optimize resources and bargaining power.[21]

An important distinction in state legislation is whether PDABs are given the authority to set UPLs. Of the 11 states that have enacted PDAB legislation, only four have granted authority to set UPLs: Colorado, Maryland (pending legislative approval), Minnesota, and Washington. Within states with UPL authority, Washington is only able to set UPLs for up to 12 drugs, while Colorado and Minnesota do not have a limit for establishing UPLs on PDAB-reviewed drugs.[14,16,17,20] Each of these states have unique processes for establishing the UPL based on a combination of cost and value measures. For example, in Washington if a drug is ruled as "unaffordable" by the board, the following must be taken into account when setting an UPL: the cost of administering the medication; the cost of delivering the drug to the patient, if the drug is included in the FDA drug shortage list; and any relevant administrative costs related to the delivery and/or production of the drug. Additionally, the board must monitor the drug for future drug shortages and can suspend the UPL should a shortage occur. Finally, the board must assess the value that the drug has for those who utilize it to enhance health and/or elongate life.[14] While each state with UPL authority has different specific requirements, they all generally follow the above-mentioned requirements. Nonetheless, at the time this report was written, no state had set an UPL.

Of important note, some state PDABs have faced legislative and legal challenges that limit their implementation. For example, in 2019, Ohio successfully passed legislation outlining the creation and implementation of a state PDAB. However, in 2021, an amendment to the statute that originally authorized the PDAB was made that essentially nullifies the state's PDAB in practice.[22] In addition to legislative challenges, PDABs are facing legal challenges, often from drug manufacturers. For example, after Colorado's PDAB ruled that the drug Enbrel® was "unaffordable," paving the way for the establishment of a UPL, the drug's manufacturer, Amgen, sued the state, claiming that the PDAB law violates several state constitutional provisions and attempts to regulate federal health care programs.[23] At the time this report was written, the outcome of this case is unknown. However, it is highly likely that more lawsuits will begin to materialize as additional states make claims of unaffordability and, in some cases, establish UPLs.

State Example: Colorado

The Council highlights Colorado as an example in this report as its PDAB is perhaps the furthest along in the process and includes UPLs authority. In 2021, legislation to establish a PDAB in

Colorado became law. The board is overseen by the Division of Insurance of the Colorado Department of Regulatory Agencies (DORA). The board consists of up of five members who have advanced degree(s) or experience in health care economics or clinical medicine and are appointed by the governor and confirmed by the state senate. The board began meeting in late 2021 and in 2024, Colorado's PDAB voted to determine the affordability of the first five drugs. This process included presentations by experts, testimony from witnesses, including open public testimony, and deliberation of the board members. Two medications were ruled as "not unaffordable" and the other three were ruled "unaffordable" to Colorado consumers. For the three medications that were ruled "unaffordable," the PDAB is working to establish UPLs. Per the original design, the board has a preset process that was anticipated to take approximately six months. However, due to certain barriers, such as legal challenges from the manufacturer, this process has been drawn out and UPLs have not yet been established for the three medications ruled "unaffordable." The first UPL rulemaking hearing was scheduled to be held in early March 2025, which will begin the process of establishing the payment limit for the specific medication.[16]

POTENTIAL IMPACTS

PDABs and UPLs are novel to the drug pricing landscape and, as a result, much of the information regarding their impact is speculative. Many states have established policies to create PDABs, but the majority of boards have either not yet started meeting or started very recently. While researchers have theorized how these boards and/or limits may impact patients and physicians, data to establish firm, research-based conclusions of the actual impacts are not available at this time.

Proponents of PDABs and UPLs explain that these strategies are designed to rein in out-of-control drug prices, ensure that patients have access to their medications at a reasonable price, and lower state drug spending.[24,25] Supporters point to similar practices in the non-medical communities, such as public utility commissions. Each state has its own public utility commission which works to regulate providers to ensure that the prices that consumers pay for public utilities are fair for all involved. While these commissions have been relatively successful in controlling utility costs, the difference between the structure of utility pricing and delivery and drug pricing and delivery is quite significant.[26] Additionally, it is a reasonably common practice for states to set payment rates for health care services to ensure they are affordable and accessible to patients. For example, fee schedules are commonly set by state and federal governments that list the maximums that a physician or provider is paid for a service. Some anticipate that PDABs and UPLs could function in a similar way to control costs.[25] Supporters of PDABs believe that by focusing on the drug payment rate specifically, patent preemption (i.e., breaking the patent) is avoided while also allowing for control of drug cost. At the core, those who champion PDABs argue that medications are exceptionally expensive and these boards will lower drug prices, thus making drugs more accessible and affordable to patients.[24,25]

While most experts agree that prescription medications in the US are prohibitively expensive, some experts have expressed concern regarding the impact that PDABs and UPLs may have on patients and physicians.[7,27] Concern has been expressed that the implementation of these boards will negatively impact patient access to medications. One specific concern centers around medication formulary placement. If a medication is given an UPL, payers may choose to place it on a less desirable formulary tier. This could result in patients not being able to access the most effective medication affordably and/or increase required utilization management for that medication.[7,27] Further, this could result in limits to physician payment and disrupt physician/practice ability to purchase medications in a fiscally responsible manner. This is especially salient if the drug's UPL is less than the acquisition cost, as purchasers would not be able to affordably stock the medication.[10]

Concern also has been raised that patient assistance programs could suffer for selected medications. These concerns are particularly salient for patients who are on essential, specified, and expensive prescriptions, especially HIV, cancer, and Hepatitis C treatments/medications.[27] For example, research has suggested that patients on HIV medications saved 91 percent of their OOP costs due to copay assistance programs. Should these medications be given UPLs, it is possible that manufacturers could reassess assistance programs. This could lead to a situation where the medication cost may be below the UPL, but patients may be required to pay greater OOP costs due to lessened or removed assistance programs.[7,27] Research has suggested that even a minor increase in patient OOP spending impacts patient adherence. For example, a recent study found that a minor increase from $0 to $10 OOP cost doubled the abandonment rate for patients using oral HIV pre-exposure prophylaxis (PrEP). This study, along with others linking increases in patient OOP costs to lower treatment adherence, exemplifies the potential impact of even a small change to programs designed to relieve patient OOP costs.[28] There is ample concern that the implementation of PDABs, especially those with UPL authority, could significantly impact programs designed to relieve patient OOP costs potentially impacting treatment adherence.[27]

Additionally, advocacy groups have recently raised concerns around the disproportionate impact of PDABs on people with disabilities. While the states that have released lists of selected medications are still relatively limited, initial lists indicate that the vast majority of selected medications are disproportionately used to treat conditions that are likely or highly likely to be classified as "disabling" under the Americans with Disabilities Act (ADA).[29,30] Even while Washington state has the lowest rate of medications used to treat potentially disabling diagnoses, it still amounts to over 86 percent. Across the published lists, each state has at least one HIV antiretroviral, with medications to treat cancer, genetic disorders, autoimmune disorders, and endocrine disorders also disproportionately represented.[29] Serious concerns have been raised that the selection of these medications could cause disparate impacts on the disability community and limit patient access to essential medications. Experts explain that the potential downline supply chain disruptions and lack of guaranteed patient cost savings, paired with the aforementioned unknown impact on patient assistance programs, could lead to significant barriers in patient access.[29,30]

While it remains to be seen how PDABs and their UPLs will impact patients and physicians, it is important to acknowledge the enforcement potential of these boards. Experts agree that while PDABs are likely very well intentioned, there is not much enforcement to back up the recommendations that are made. This is especially relevant for states that have not granted UPL authority to their PDAB. However, even among the states that have given authority to grant UPLs, there are significant questions as to whether these limits will impact actual drug prices. For example, there is current discussion as to whether these UPLs will apply to insurers that are not regulated by the state. In other words, federal or interstate plans may be outside the scope of authority for state PDABs.[23,31] Without effective enforcement, which no PDAB seems to have at the present time, it is unlikely that manufacturers, payers, and PBMs will adhere to the suggested prices.

AMA POLICY AND ADVOCACY

The AMA has a robust body of policy to ensure that prescription medications are affordable and accessible to patients. Specifically, Policy H-110.997 outlines support for programs that are designed to mitigate the cost of prescription medications, physician autonomy to prescribe the most appropriate and effective medication to their patient, and for payers to cover prescribed medications. Policy H-110.987 builds on the aforementioned policy to ensure that pharmaceutical companies and their proxies are not participating in anticompetitive behaviors or mergers/acquisitions that unduly raise the cost of prescription medications. This policy also

addresses the need to ensure that prescription prices are reasonable and do not exceed the pace of inflation. Policy H-330.864 focuses specifically on reforming Medicare drug reimbursement and ensuring that it is done in a manner that allows for patient access and also reimburses physicians fairly. Finally, Policy H-100.964 outlines AMA support to ensure that prescription medications are covered by payers in a manner that keeps them affordable and accessible to patients.

Additionally, the AMA has a robust history of drug pricing advocacy. Over the last few years, numerous letters and testimonies have been sent to regulators (CMS 2023, CMS 2024), legislators (House 2023, House 2023(a), Senate 2024), and payers (NAIC 2023) working to mitigate the high price of prescription drugs and ensure that patients are able to afford their medications. In addition to this advocacy work, the AMA has a longstanding grassroots campaign, TruthinRx, that is designed to increase transparency of drug pricing and decrease costs.

In addition to policy and advocacy surrounding drug pricing, AMA policy addresses concerns raised by sceptics of PDABs and UPLs. The AMA has a long history of working to lessen utilization management, especially prior authorization via campaigns (e.g., Fix Prior Auth) and policy. Specifically, Policies H-320.939 and D-320.982 outline the AMA's stance against prior authorization and efforts to ensure that physicians are not overburdened by these requirements. Additionally, Policy H-125.991 outlines the AMA's efforts to ensure that payer formularies are fair and inclusive of physician-prescribed medications.

DISCUSSION

Proponents of PDABs believe that they will do what they intend—lower drug prices in the U.S. and create a more affordable system for patients. However, critics voice concerns around the actual impacts. Concern has been expressed that PDABs, especially those with the authority to establish UPLs, may increase physician administrative burden, increase costs for patients and physicians, and disproportionately impact patients with ADA disabling conditions. Additionally, concerns have been raised that if UPLs are set below the acquisition cost for a physician administered drug, there may be an adverse impact on medication availability and could result in market distortions. Others question the actual enforcement authority these boards have, or will have, on regulating drug prices. Since PDABs and UPLs are relatively new, it will take time to see if these strategies result in their intended goal—to lower drug prices and make prescription medications more affordable for patients.

CONCLUSION

The Council believes that the AMA has robust advocacy efforts and clear policy supporting the need for prescription drugs to be affordable and accessible to patients. However, due to the relative recency of PDABs, there is no research yet available on actual impacts or outcomes of the boards. Therefore, the Council will continue to monitor this issue and report back when a reasonable body of research has been established in which to form conclusions and guide additional, well-informed policy on the impact of PDABs and UPLs on patients and physicians.

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Appendix A
State Prescription Drug Affordability Boards

State	Initiative	Budget/Funding	UPL Authority?	Membership	Populations	Drug Inclusion Criteria
Colorado	CO SB 175-2021	State budget line. *Approximately $750,000/year.*	Yes.	2 FTE and 2 PTE employee allocation. Additional contractors approved with board review. Additional $250,000 allocated. The Board consists of 5 members appointed by the governor and confirmed by the senate. All must have either an advanced degree and experience or expertise in health care economics or clinical medicine.	All consumers. *Exemption for state funded plans that choose to opt out.*	Drugs that meet 3+ of the following: - Brand-name drugs and biologics that have a wholesale acquisition cost (WAC) of $30,000+ - Brand-name drugs and biologics that have a WAC increase of 10%+ in the last 12 months - Biosimilars that launch at a WAC that is not at least 15% less than the reference - Generics that have a WAC of over $100/30 days
Maine	ME LD 120 (2021)	Absorbed by existing budgets.	No.	0 FTE. Board supported by the Office of Affordable Health Care. The Board consists of 13 members, 6 appointed by the Senate President, 5 by the Speaker of the House, 2 state commissioners (non-voting).	Public plan beneficiaries.	Drugs that are purchases by public payers and may cause "affordability challenges."
Maryland	MD HB 768-2019	Start up costs provided by the State budget. Annual funding from fees on drug manufacturers, PBMs, carriers, and wholesale distributors. *2024*	Yes. *If legislative approval is gained.*	5 FTE and 1 PTE. Additional contractors approved with board review. Additional $250,000 allocated. The Board consists of 5 members appointed by the governor, President of the Senate, Speaker of the House, Attorney General, and jointly	Public plan beneficiaries. *Have indicated potential to attempt expansion to all payers.*	Drugs that meet the following criteria: - Brand-name that launch with a WAC of over $30,000/yr - Brand-name with a price increase of $3,000+/year - Biosimilars that launch at a WAC that is not at least 15% less than the reference

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Appendix A
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		budget: 1.4 million+		by the House Speaker and Senate President.		- Generics that have a WAC of over $100/30 days OR increased by 200%+ in the last year
Massachusetts	HB 4000 – Section 46 of FY 2020 Budget	No additional funding appropriated.	No.	Implemented through MA Medicaid agency and Health Policy Commission.	Medicaid beneficiaries.	Drugs covered by Medicaid that cost more than $25,000/yr per person or $10 million to the program. Excludes medications in which a supplemental rebate agreement is reached.
Minnesota	MN SF 2744-Section 62J.85	Base appropriation of at least $500,000/year from the State budget.	Yes.	1 FTE with the potential for more. Board to be supported by the Commissioner of Health and Attorney General. The Board consists of 9 members. 7 voting members appointed by the governor, 1 nonvoting member appointed by the senate majority leader, and 1 nonvoting member appointed by the speaker of the house.	All consumers. *Plans preempted by ERISA can choose to opt out.*	Drugs that meet the following criteria: - Brand name/biologics that have a WAC increase of over 15% or more than $3,000 annually or during the course of treatment after adjusting for Consumer Price Index - Brand name/biologics with a WAC of over $60,000 per year or course of treatment - Biosimilars that launch at a WAC that is not at least 20% less than the reference - Generics that have a WAC of over $100/30 days, a course of treatment, or one unit - Generics that have a price increase by 200%+ in the last year The Board may identify additional drugs that impose significant affordability challenges.
New Hampshire	NH HB 1280-2020	Appropriation of approximately $350,000/annually.	No.	N/A The Board consists of two members appointed by the president of the senate, two members appointed by the speaker of the house, and one appointed by the governor.	Public plan beneficiaries.	Drugs that are purchases by public payers and may cause “affordability challenges.”

Appendix A
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New Jersey	P.L. 2023, c. 106	Appropriation of $1.5 million to implement the initial bill.	No.	The Board consists of 5 public members; 3 appointed by the governor; 1 on recommendation of the senate president, and 1 on recommendation of the house speaker. Will work in tandem with the Drug Affordability Council/Drug Affordability Unit.	N/A	Drug practice reports are reviewed and the board is able to make recommendations to increase affordability.
New York	PHL Sec 280-2017	No additional funding appropriated.	No.	Implemented through NY Medicaid Agency's Medicaid Drug Benefit Cap.	Medicaid beneficiaries.	- Drugs that will exceed the state's Medicaid drug cap (set annually) - Newly launched drugs that are "high cost" or meet the following o Brand-name that launch with a WAC of over $30,000/yr o Brand-name with a price increase of $3,000+/year o Biosimilars that launch at a WAC that is not at least 15% less than the reference o Generics that have a WAC of over $100/30 days o Gene therapies
Ohio	OH HB 166-133 2019	N/A. 2021 amendment to the authorizing statute mitigated authority. Board is still technically intact.	No.	The board is comprised of 17 individuals. 6 state employees (director of administrative services; director of health; Medicaid director; director of mental health and addiction services; administrator of workers' compensation) and 12 members who work in drug affordability and availability and are appointed by the governor, senate	N/A.	Not focused on specific drugs, instead the Board is tasked in creating reports including the following information: - How the state can best achieve drug price transparency - Avenues/payment models to increase/create affordability - Levering the state's purchasing power - Creating efficiencies to reduce costs

Appendix A
State Prescription Drug Affordability Boards

				president, and house speaker (3 appointments each).		- Outcomes to be measured to improve state's purchasing of drugs - How existing resources cab be optimized
Oregon	OR SB 844-2021	$1.7+ million appropriated to the Department of Consumer and Business Services with the intent for reimbursement from manufacturer fees. The ongoing budget will come from fees.	No.	5 FTE. The Board consists of 5 members all appointed by the governor.	N/A.	Nine drugs and one insulin product each year based on drugs reported in OR's Prescription Drug Price Transparency Program. Excludes any drug designated by the FDA to treat a rare disease/condition.
Washington	WA SB 5532/Chapter 153-2022	Initial appropriation of $1.5 million over the first 3 years.	Yes. *For up to 12 drugs.*	4 FTE. The Board consists of 5 members appointed by the governor with expertise in health care economics or clinical medicine.	All consumers. *Exemption for state funded plans that choose to opt out.*	Drugs that have been on the market for 7+ years, are not designated by the FDA to treat a rare disease/condition, and meet the following criteria: - Brand name/biologics with a WAC of over $60,000 per year or course of treatment - Brand name/biologics that have a WAC increase of over 15% over 1 year or 50% over 3 years - Biosimilars that launch at a WAC that is not at least 15% less than the reference - Generics that have a WAC of over $100/30 days, a course of treatment, or have a price increase by 200%+ in the last year
Adapted from the NASHP Comparison of State Prescription Drug Affordability Review Initiatives and source legislation.						