HAYDEN

State Initiatives to Control Access to Medicine:

Implications of Prescription Drug Affordability Boards on Therapeutic Treatment Options

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EXECUTIVE SUMMARY

States are enacting laws that allow unelected Prescription Drug Affordability Boards (PDABs) the authority to implement price controls on medicines they deem unaffordable or too high priced. However, in practice, PDABs are focused on state budget cost-cutting rather than patient out-of-pocket costs and access to medicines and are likely to have negative implications on clinical outcomes and access to needed treatment options. PDABs lack robust evidence standards, do not fully consider the clinical value of treatments, and rely on unelected officials with little to no medical expertise to evaluate clinical benefits and consider patient needs. Moreover, they add a layer of unelected bureaucracy that can interfere with the relationship between patients and their physicians.

This paper details PDAB cost reduction strategies and their consequences on access to medicines. We consider how PDABs may limit patient access to therapeutic treatment options and are unlikely to reduce out-of-pocket costs for patients.

Overview of PDABs

Since 2019, 11 states have passed legislation establishing PDABs[1] with one consistent objective: to place restrictions on the cost of certain drugs and lower patient or state health care costs.[i] While the intent is to make drugs more affordable, in implementation, PDABs may reduce access to medicine without meaningfully reducing healthcare costs. Prescription drug spending is only 6% to 15% of total healthcare costs (depending on age and insurance type), whereas hospital procedures and other services represent more than 40% of spending.[ii] Additionally, evidence shows medicines can prevent disease complications and the need for other costlier aspects of care such as ER visits, hospital stays, and long-term care. [ii] As such, restricting access to recommended medicines can increase health care costs.

PDABs have variable levels of authority granted through state legislation and are often given significant leeway for unelected members to make decisions in implementation. State PDABs may have the authority to set upper payment limits (UPLs) (or a price ceiling) on branded medications, set annual state spending targets, negotiate Medicaid supplemental rebates with manufacturers, or identify other policies to control drug spend.[iii,iv] In some states, a PDAB UPL has the potential to exercise domain over state-

[1] While most are called PDABs, other names are used, such as NJ's PDAC (Prescription Drug Advisory Council)

regulated commercial markets - including exchange plans or state employee benefits - in addition to government payor health plans.[v,vi]

State-specific variation across PDAB functions and requirements, such as mandatory expertise of board members, inputs to assess drug affordability, thresholds to measure drug affordability, criteria to evaluate cost effectiveness, etc., results in unpredictable evaluations and prices for medicines and complicate stakeholder incentives. This unpredictability also complicates risk management for wholesalers, hospitals, providers, pharmacies, Pharmacy Benefit Managers (PBMs), and manufacturers, and may result in decreased patient access to therapeutic options.

Upper Payment Limits (UPLs)

Of all cost restrictions that state PDABs are authorized to exercise, UPLs, or "price ceilings" for in-state payers, can have the most significant impact on pharmacies, physicians, and patients.[vii] A UPL sets a maximum price[2] that in-state payers can pay for a medication. Currently, four states[3] have legislation granting PDABs the authority to establish UPLs, however specific UPL authority varies based on state law.[viii] For example, in Minnesota, if the PDAB determines a drug to be unaffordable and a UPL is set, the UPL will refer to the "federally negotiated Medicare maximum fair price for any drug with a Medicare maximum fair price", which follows an opaque process that has been significantly criticized for ignoring patient values.[ix,x]

Colorado's PDAB was the first to declare a drug to be unaffordable when in June 2024 it determined three widely used drugs were unaffordable, all of which now face the possibility of a UPL.[xi,xii]

Having Treatment Options is Important for Health and Costs

The extent to which government actions improve health for patients will depend on whether they improve and not hinder the availability of treatment options for different patient clinical needs. The ability to choose between multiple therapeutic options enables healthcare providers, in partnership with patients, to develop treatment plans that are unique to that individual patient's physiology and disease state. For example, having a range of treatment choices is important to address variable treatment response or

[2] This maximum price is determined by the PDAB after an affordability assessment or policy review that deems a drug unaffordable and requiring a cost containment measure; PDABs are not required to engage manufacturers in such decisions.
[3] States with legislation granting PDABs the authority to establish UPLs include Colorado, Minnesota, Washington, and Maryland.

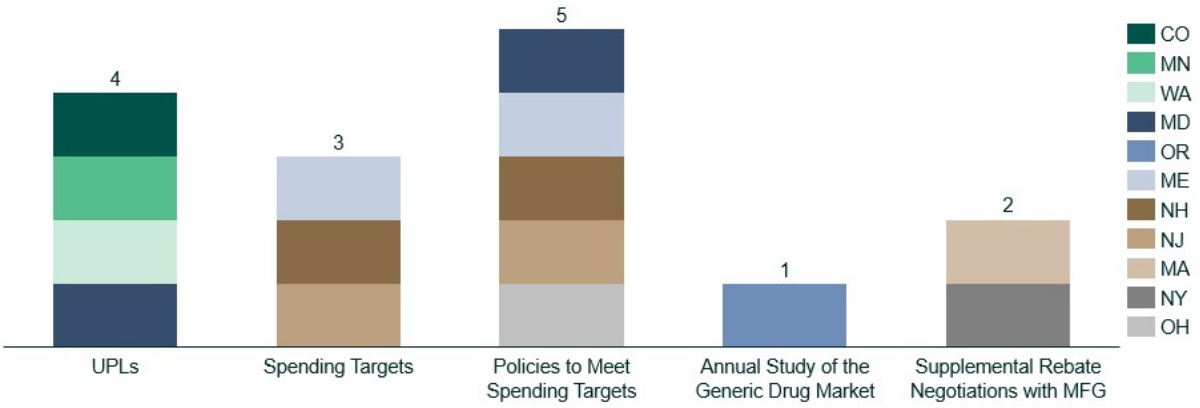
tolerability, manage co-morbidities and mitigate against certain interactions or adverse events, and to provide options to combat treatment resistance or diminishing treatment effect.[xiii] When patients and care providers are given more options, better health outcomes can be achieved due to increased effectiveness, improved patient clinical response, reduced side effects, and increased adherence.[xiv]

Greater patient choice can result in longer-term cost savings, as patients are more likely to better manage their illness and less likely to require a medication switch or follow-up health care encounters. In fact, better disease management achieved through use of prescription medicines has long been credited with avoiding health complications and spending on other costly health care services such as ER visits, hospital stays, surgeries, and long-term care.[xv] Treatment choice is particularly important for patients managing chronic diseases, which are the single largest driver of health care costs in the U.S., representing 90% of the nearly $4 trillion spent on healthcare each year.[xvi] A one-size-fits-all treatment approach will limit Americans' ability to manage their health and optimize management of their illnesses through treatment choice.

Example reasons patients need access to multiple therapeutic options:

1. Differences in patient response can vary for an individual medicine.
2. Treatment resistance develops when patients experience diminishing response to a therapeutic dose of a treatment.
3. Tolerability and adherence to treatment can vary from patient to patient.

PDAB Authority by State [xviv, xvv]



Impact on Patient Access to Therapeutic Options

While PDABs were created by lawmakers with the primary goal of improving medicine affordability for patients, the goal of PDABs has effectively shifted to management of overall state budget, cost-cutting, and a focus on insurer costs. The structure and management of PDABs may not lower healthcare costs and risk overlooking and undervaluing clinical drug attributes resulting in reduced access to medicines critical to diverse patient populations. By adopting flawed methods with poor data and prioritizing cost containment over patients' unique clinical needs, affordability reviews mischaracterize medicines as "unaffordable" while ignoring other aspects of health care that are in fact inaccessible and unaffordable to patients . Also, once a UPL is set the requirement is on payers and purchasers to not pay more than the price ceiling, but they may not be able to secure sufficient supply to meet the health needs of the states' population at that price. Two PDAB functions challenge a patient's ability to access to therapeutic options:

1. Drug affordability assessments, which may not adequately assess the value of medicines or recognize the importance of different medicine options to treat individual patients' unique clinical needs, and
2. UPLs, which can limit payer coverage and pharmacy/physician/hospital stocking of medicines, including all drugs that treat similar diseases to those impacted by a drug with a UPL.

Flawed drug affordability assessments

PDABs' drug affordability assessments are conducted to determine which medications are considered unaffordable and in scope for future restrictions. PDABs have established different approaches to do so and often these defined approaches omit critical considerations or contain other flaws. Flawed affordability assessments may lead to misguided price controls that can ultimately harm patient access to treatments. Affordability assessments can be problematic because of:

- Inconsistent methodology used by each state PDAB
- Limited focus on patient outcomes
- Reliance on biased and inaccurate data
- Limited incorporation of the patient perspective
- One-size-fits -all approach – standardized affordability benchmarks that ignore differences in treatment modalities (injectables vs. pills; inpatient vs outpatient administration)

- Prioritization of state cost savings over long-term clinical outcomes
- Broad leeway for PDAB members to make decisions without oversight
- PDAB board members who lack healthcare economic, clinical, and data science subject matter expertise

The methodologies PDABs use to determine affordability are not consistent and can include numerous different measures such as cost, clinical evidence, therapeutic alternatives, comparative effectiveness, economic evaluation, anticipated market dynamics, and patient out-of-pocket cost.[xvii] Datasets required to inform these areas of assessment are limited,[xviii] require PDAB board members to be able to navigate complex healthcare economics, often without this expertise, and frequently include limited, inaccurate, biased, or discriminatory metrics that work against patients.[xix, xx] For example, one recent study conducted by Community Access National Network (CANN) revealed "PDABs are disproportionately targeting medications used to treat conditions highly likely or likely to be classified as disabilities under the ADA"[4].[xxi] Because PDABs are usually focused on assessing affordability by measuring the cost of therapies to the state and not on value delivered to the patient, affordability assessments do not consistently consider the downstream savings that could result from a medicine that has a higher list price. PDABs do not contextualize the prescription drug cost relative to other potential health system savings including, for example, reduction in urgent care and ER visits, reduction in in-patient days, and decreased requirements for specialist visits.

Price controls or UPLs can limit payer coverage and the stocking of medicines

PDABs can impact patient access to treatment as drugs exceeding their established price threshold may not be on formulary or stocked in a pharmacy.

PDABs also impact patients' medication options by setting UPLs impacting branded, biosimilar, and generic medications. Although a UPL may yield some decrease in prescription drug costs for the state, it will result in consequences that ultimately risk patient access to treatments and do not guarantee patient savings. Some cost savings may be realized for the states because people stop taking medicines. For example, PBMs that administer drug benefits are incentivized by a number of economic factors, including rebates. But a UPL changes the economics for PBMs, by replacing private market discounts and rebates with a controlled price which may incentivize them to impose restrictions resulting in significant access challenges for patients. These challenges often involve a range of utilization management

[4] ADA stands for Americans with Disabilities Act

tools used by insurance companies and PBMs to control costs, such as prior authorization requirements or step-therapy protocols, where patients are required to try and fail on one or more lower-cost or preferred medications before gaining access to a more expensive or non-preferred treatment prescribed by their physician. Additionally, patients may face increased out-of-pocket costs and restrictive formulary designs that limit access to medication unless approved through a medical exception.[xxii] A recent white paper[xxiii] released by the Partnership to Fight Chronic Disease (PFCD) includes interviews from health plan executives confirming that:

"A UPL affects insurers and PBMs directly, not patients. Insurers, PBMs and other payers, in turn, will continue to make the decisions about what patients pay out-of-pocket and any conditions patients must meet for coverage like requiring step therapy or prior authorization… Insurers confirm what patient advocates fear: UPLs will not lower patient costs and will increase barriers to access."

A UPL might also require pharmacies to manage inventory differently. Pharmacies are challenged to respond to UPLs because despite the State imposing a pricing limit, this does not mean the drug's purchase price has reduced. With pricing limits, pharmacies may be left to dispense drugs to patients at a lower price than the drug's acquisition cost,[xxiv] which may lead to pharmacies not stocking medications with a UPL.[xxv] This concept could apply to others that dispense medicines to patients like physicians and hospitals.

Select Therapeutic Areas Demonstrate Why Options are Key to Patient Health

Depression (SSRIs)	Selective serotonin reuptake inhibitors (SSRIs) for the treatment of major depressive disorder are more easily tolerated and safer than earlier classes of medications.[xxviii] In clinical trials, SSRIs show similar efficacy, however, a substantial number of patients who fail to respond to, or who are unable to tolerate the first SSRI they receive, will achieve a clinically meaningful response when switched to another drug in the same class.[xxix,xxx,xxxi] As such, patients' ability to work with their physician to determine which SSRI they are best able to tolerate, without access restrictions, is critical.

Parkinson's Disease	Because there is no cure for Parkinson's disease, drug therapy is designed for symptom management and to improve the patient's quality of life. Selection of drug therapy is dependent upon many factors, including stage of disease, symptoms, level of disability, age, and side effect profile of the drug being considered.[xxxii] It is critical for Parkinson's patients and their doctors to be able to access available options as patients experience progression in the disease or as their treatment goals shift.
Schizophrenia (SGAs)	Second generation antipsychotics (SGAs) are used to treat delusions and hallucinations, negative symptoms, and cognitive deficits in those with schizophrenia. The mechanisms of action and side-effect profiles differ substantially between SGAs and many patients switch from one antipsychotic to the next because it is very difficult to predict how a patient will respond or tolerate specific drugs.[xxxiii,xxxiv] As individuals with schizophrenia navigate the challenges of their disease, it is essential that they are able to work with their physicians to determine the medication which best addresses their symptoms and cognitive deficits while limiting undesirable side effects.
Diabetes (DPP-4 Inhibitors)	Dipeptidyl-peptidase-4 (DPP-4) inhibitors or "gliptins" are used in the treatment of type 2 diabetes. The options for treating type 2 diabetes are varied, and patients frequently present with comorbid conditions. Labeling differences between different DPP-4 inhibitors call for different levels of monitoring of certain comorbid conditions,[xxxv] and patients and physicians may select medicines within the class based on the desire to minimize dose adjustments. Treatment decisions around type 2 diabetes may also involve decisions about which classes of medicines to use based on efficacy, tolerability and adherence.[xxxvi]
Breast Cancer (CDK4/6 inhibitors)	CDK4/6 inhibitors are used to treat specific types of hormone receptor-positive, HER2-negative breast cancer. Breast cancer remains the most common cancer among women, and, for women, breast cancer is the second-leading cause of cancer-related death. The role cyclin dependent kinases play in breast cancer has been understood for decades, but earlier generations of CDK-targeting compounds had poor selectivity and high toxicity, driving the research that led to the CDK4/6 inhibitors, which are more specific. However, there are differences between approved CDK4/6 inhibitors, making the choice of treatment a critical decision that patients must make with their care team, based on "patient characteristics, potential comorbidities, and concomitant medications."[xxxvii]

Future Considerations

Despite the intent of PDABs to reduce patient prescription drug costs, PDABs threaten to worsen patient access to care and have implications for patient health outcomes. PDAB UPLs put patients at risk with unelected boards with- little to no medical expertise making decisions that will result in health plans more tightly restricting access and pharmacies struggling to stock medications. Healthcare providers (HCPs) may have fewer therapeutic options to prescribe, decreasing potential effectiveness or tolerability of treatment for their patients.[xxvi] As states evaluate policies aimed at managing healthcare costs, patient access to medicine and therapeutic treatment options, should remain the primary objective to realize better health. Meaningful cost containment will not be achievable with UPLs on medicines.

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