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Prescription Drug Affordability Boards (PDABs): What Are They and Why Should Advocates Care about Them?

Prescription drug access and pricing have been in the policy spotlight at the federal level over the past few years, with Congress taking unprecedent steps to respond to high prescription drug prices in Medicare through passage of the Inflation Reduction Act (IRA) in 2022. But state governments are also finding ways to address the rising costs of drugs. One mechanism states are using to evaluate and curb the prices of certain high-cost drugs are Prescription Drug Affordability Boards (PDABs). A PDAB is an independent board made up of experts tasked with analyzing—and in some cases, acting to reduce—high drug prices in the state. Read on to learn more about PDABs and how their decisions may impact individuals who rely on high-cost medications to stay healthy.

What is a PDAB and How Does It Work?

PDABs are independent entities created at the state level, primarily through state legislation, charged with taking certain actions to lower the cost of drugs. States can structure their PDABs in different ways, including deciding which insurers PDAB actions will affect, what drugs the PDAB will focus on, whether and how to place an upper limit on a drug's price, and what data reporting and transparency requirements manufacturers must meet.

Scope of payers

- Some states limit affordability review to certain payers (e.g., Medicaid and state employee health benefits)
- •Other states also include commercial payers regulated by the state

Drug selection •States set criteria to select drugs for review, including average patient cost sharing for the drug, accessibility of patient assistance programs to help with cost sharing, and availability of affordable therapeutic alternatives

Upper paymen limit

- •Some states have authority to set an upper payment limit for a drug under review
- •Other states only have authority to recommend payment limits or state policies to lower the cost of certain drugs

Data reporting

 Most states that have enacted PDABs have also included transparency provisions, including public reporting of drug pricing trends



PDABs have started to gain traction around the country, and the National Academy of State Health Policy (NASHP) is tracking which states have pending and final legislation creating or granting authority to a PDAB.

PDABs in Action: Opportunities and Challenges

Maryland enacted legislation creating the first PDAB in 2019. Since then, a <u>handful of other states</u> have followed suit. Though this policy intervention is still relatively new, we are starting to gain insights into how PDABs are operating and the challenges they've encountered in taking on the daunting task of addressing drug pricing and access.

Addressing a growing need

KFF polling has consistently found that prescription drug affordability remains the number one health policy issue for consumers across the country, with more than one in four respondents in 2023 reporting difficulty affording their medication. States are also grappling with the growing state budget impacts of high drug prices and are eager to follow the lead of the federal government in seeking policy solutions to this problem. The creation of PDABs is therefore a response of state legislators to the voices of constituents and others negatively impacted by high drug prices.

The first action of PDABs has been to assess the drug pricing landscape both nationally and in the state, including analyzing state drug spending trends, year-on-year list price increases, and consumer reports of affordability challenges among many other variables.

Identifying drugs for review involves a complex set of factors

So far only one state PDAB – Colorado – has identified a drug to which an upper payment limit will be applied. In Colorado, this upper payment limit will apply in Medicaid, the state employee health benefit plan, and commercial plans regulated by the state.

The process Colorado used to identify the first drugs that will be subject to an affordability review (and potentially upper payment limits) may be instructive for other states. The state used a number of criteria, including: average patient out-of-pocket costs, drugs that had

Wholesale Acquisition Cost (WAC)

WAC is the **list price** paid by a wholesaler or distributor for drugs purchased from a manufacturer.

an annual wholesale acquisition cost (WAC) of \$30,000, drugs that had an annual increase in WAC of \$3,000, and health equity impact of affordability challenges. Using these metrics, Colorado identified five drugs, listed in the table below, as potential targets of payment limit action.

Colorado PDAB Prioritized Drug List (2023)			
Drug	Average annual patient out-of-pocket (OOP) cost	Average total annual cost per patient (including costs paid by insurers)	
Cosentyx (psoriasis, psoriatic arthritis)	\$2,168	\$39,335	



Trikafta (cystic fibrosis)	\$1,732	\$203,924
Enbrel (rheumatoid arthritis)	\$2,812	\$42,475
Stelara (plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis)	\$1,399	\$61,969
Genvoya (HIV)	\$1,293	\$29,090

Once the Colorado PDAB identified these five drugs, it immediately began the process of deciding whether an upper payment limit is appropriate and, if so, what that upper payment limit should be. At the end of February 2024, the Colorado PDAB voted that Enbrel will be subject to an upper payment limit. This decision kicked off a months-long process to determine this amount. The criteria the Colorado PDAB will use to determine the upper payment is set forth in regulations, and the PDAB is prohibited from considering research or methods involving Quality Adjusted Life Years (QALYs) or similar measures in setting upper payment limits. Largely because of the efforts of disability advocates, other states have similar protections in their PDAB legislation.

Other states that have authorized upper payment limits include Washington, Oregon, Maryland, and Minnesota, though they are still in the information-gathering phase of the PDAB process.

The Case against Quality Adjusted Life Years (QALYs)

Disability advocates have long <u>argued</u> that using QALYs – which is a way to measure the cost effectiveness of a drug or other health care intervention – devalues the lives of people with disabilities and/or chronic medical conditions. This is because treatment that extends or improves the lives of these communities may result in fewer QALYs than a treatment developed for a younger and healthier population where the treatment is may achieve a different level of health.

Patient groups have raised concerns about PDAB decisions affecting access to drugs

As PDABs have started debating which drugs will be subject to upper payment limits, patient groups have jumped forcefully into the mix raising concerns about possible unintended consequences of well-intentioned drug affordability policies. For instance, some groups have noted that subjecting drugs used to treat relatively rare conditions may actually limit access to these drugs for the people who need them most.

These policy tensions have recently come to a head in Colorado. Some patient advocates for cystic fibrosis, for instance, <u>argued</u> that because the disease affects a small number of patients, the PDAB should consider the outsized impact that pricing caps will have on manufacturers' willingness to continue participating in affected markets, and potentially to even make these lifesaving drugs at all. Cystic fibrosis advocates <u>applauded</u> the decision of the PDAB to ultimately not pursue an upper payment limit for Trikafta, one of the five drugs the PDAB was considering for potential action. Similarly, HIV advocates in the state also urged the PDAB to take Genvoya off of their list, arguing that existence of ADAP and copay assistance programs, coupled with the fact that there are more alternatives to Genvoya than there had been in the past, means that the drug is in fact



affordable for Coloradans and does not necessitate a price cap, which could disrupt a precarious safety net that, while not perfect, is working relatively well for HIV treatment in the state. The Colorado PDAB ultimately decided not to pursue upper payment limits for these two drugs.

The nuanced policy debate on whether an upper payment limit was appropriate for these two drugs, however, has shone a spotlight on the complex dynamics of the drug pricing ecosystem and the way safety net providers and programs operate within it. Future PDAB decisions will have to take into account this ecosystem and short and long-term consequences that payment changes will have.

What's Next?

PDABs are still a relatively nascent development and many are still in the early phases of defining the scope and scale of their role. Colorado may provide lessons learned on the opportunity for PDABs to rein in prescription drug prices as well as the extent to which PDABs can influence a gargantuan drug pricing ecosystem. All eyes will be on Colorado as they enter the complex phase of setting an upper payment limit for their first selected drug, Enbrel. There are a handful of other states closely behind Colorado looking to take a swing at prescription drug pricing through PDABs, and it will be important to watch how these efforts evolve over time.

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