



# **GCOA Alliance for Health Innovation Policy Brief: The Risks of Drug Pricing Policies and the Importance of Innovation for Healthy Aging and Patient Access**

*How State & Federal Price-Setting  
Policies Impact Access to Care &  
Innovation*

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## Introduction

Across the United States, many patients and policymakers are increasingly concerned about rising healthcare costs. While much of the focus has centered recently around price-setting provisions in the Inflation Reduction Act (IRA), a growing number of states have advanced or proposed policies to review the cost of prescription medicines within their state lines. Many of these policies have taken the form of bodies that can set the cost of certain prescription medicines, including Prescription Drug Affordability Boards, commonly known as PDABs. PDABs are often described to legislators and constituents as a way to lower costs for patients in their state, often taking the shape of a third-party board of appointed members who periodically assess the “affordability” of specific drugs.<sup>2</sup> While PDABs are often positioned as a solution to lower costs for patients, in practice there are significant flaws in the current approach.

Boards must focus on methods to directly reduce out-of-pocket costs for patients, informed by meaningful engagement from impacted communities throughout the affordability review and decision-making processes. In doing so, boards must also ensure they safeguard patient access to critical medicines today and in the future, and do not threaten to institute barriers to care that could ultimately lead to higher patient costs. Despite patients voicing concerns around potential consequences of PDAB efforts, the implementation and review processes to advance these boards in the first few states to do so have failed to address these critical considerations. While establishing a PDAB has become the common approach for states to implement drug price setting, many states are now adopting policies that bypass Board review entirely. This shift removes opportunities for meaningful input from patients and providers. Moreover, because these policies still rely on setting an upper payment limit, they pose the same challenges to patient access.

## Key Terms<sup>1</sup>

**Drug Price-Setting:** Government measures that regulate or negotiate the prices of prescription drugs, often positioned as tools to improve affordability and access for patients. Approaches may include price caps, reference pricing, or direct negotiation (such as through Medicare at the federal level), aiming to control costs.

**Prescription Drug Affordability Board (PDAB):** A state government-appointed board that has the authority to review prescription drug costs and determine if they present an affordability challenge for patients.

**Upper Payment Limit (UPL):** A ceiling amount that a healthcare payer (e.g., Medicaid, commercial insurer) can reimburse for the purchase of a medication that a PDAB deems to be unaffordable.

## Four Critical Patient Concerns With PDABs

This brief will highlight key concerns raised by patients surrounding PDABs and their ability to set prices for prescription medicines, and explore perspectives, findings, and resources that highlight their impact on access, equity, and healthy aging.

First, PDABs have been provided with a singular tool to set prices for drugs they deem unaffordable: an upper payment limit (UPL). A UPL is ceiling amount that a healthcare payer, such as Medicaid or a commercial insurer, can reimburse a provider or clinic for the purchase of a medication that a PDAB deems to be unaffordable. UPLs are more aligned with cost containment strategies for states rather than lowering patient costs at the pharmacy counter. Six years after the establishment of the first PDAB, patients are still waiting for the board to deliver on their promise of lower patient out-of-pocket costs for prescription drugs. This is also the case in other states that have established a PDAB since then.

Second, PDABs' review processes can harm the patients who need access to drugs and therapeutics the most, introducing significant health equity concerns. States such as Colorado, Maryland, and Oregon have selected drugs to undergo "affordability reviews," which disproportionately impact patients who are managing hard-to-treat conditions and aging populations. As a result of PDAB efforts in these states, the very medications developed and brought to market, which are currently demonstrating efficacy to enable us to lead healthy and productive lives, are subject to arbitrary cost review processes with unproven benefits to patients.

Across states with prescription drug affordability review initiatives such as PDABs, those patients enrolled in public plans – Medicaid populations in particular – will be disproportionately impacted, which threatens to further widen health disparities within the U.S. population.<sup>3</sup>

- *Relative to White children and adults, Medicaid covers a higher share of Black, Hispanic, and American Indian and Alaska Native (AIAN) children and adults.<sup>4</sup>*
- *Medicaid covers 40% of non-elderly adults with HIV in the U.S.<sup>5</sup>*
- *In 2021, Medicaid covered four in ten children, eight in ten children in poverty, one in six adults, and almost half of adults in poverty.<sup>6,7,8,9</sup>*
- *Independent pharmacies are essential for rural and older populations, but caps and price-setting policies threaten their ability to provide access to prescriptions for over 15 million Americans who rely on these community-based providers.<sup>10</sup>*

Medicaid beneficiaries are more likely to have a chronic disease compared to patients not enrolled in Medicaid.<sup>10</sup> Should PDABs consider and select drugs for affordability reviews based on the conditions faced most frequently by this patient population, they threaten to stunt innovation and the discovery of future treatments for conditions such as heart disease, cancer, and HIV.

**Third, PDABs have the potential to reduce access to critical medications, with strong negative impacts on healthy aging.** According to the 2020 Census, the U.S. population aged 65 and over grew nearly five times faster than the total population over the 100 years from 1920 to 2020. Our country's rapidly growing aging population signals a need for solutions that promote innovation that can keep individuals working and contributing for longer, rather than policies that threaten patient outcomes and increase the burden on our healthcare system.

**Fourth, PDABs are established to improve affordability for patients. However, in practice, UPLs are not a proven tool to reduce patient out-of-pocket costs. The debate within PDABs centers around improving affordability for patients but boards must mitigate the potential for patient risk and harm to health outcomes in the name of cost containment for states.** For patients, affordability differs depending on an individual's health status and numerous other factors in their lives. Despite access to life-saving and life-extending medications hinging upon PDAB's definition of affordability under the current model, boards have largely been unable to strictly define this criteria. In June 2024, the Oregon PDAB opted to halt all drug affordability reviews for the remainder of the year and regroup in 2025, so that, among other things, the Board could determine what affordability means. Prior to this, the Board was undertaking drug reviews without a clear definition of the very variable they were seeking to assess.

PDABs are a short-sighted, often politically-driven, policy primarily focused on cost containment for the state rather than meaningful benefits for patient communities. All too often, PDABs are implemented in a way that ignores the long-term implications of drug price setting, such as through the use of a UPL, in favor of more immediate savings in a state's budget.

Good health policy must result in improved health outcomes for underserved and vulnerable populations, and to date PDABs have not met that objective. The current landscape, including input from patients, providers, and other impacted stakeholders, makes clear that these boards must do more to engage trusted partners and impacted populations to ensure patients benefit.

*"The mission of NMQF is to reduce patient risk by assuring optimal care for all. NMQF's vision is an American health services research, delivery, and financing system whose operating principle is to reduce patient risk for amenable morbidity and mortality while improving quality of life. PDAB's with UPL authority risk assigning a higher valence to the costs of prescription drugs rather than the assurance of best possible outcomes for all patient cohorts."*

Gretchen C. Wartman, Vice President for Policy and Program, National Minority Quality Forum (NMQF)

**Table 1: PDABs across the United States\***

8	<b>Eight states have enacted PDAB legislation.<sup>1</sup></b> <ul style="list-style-type: none"><li>Four states (CO, MD, MN, WA) have PDABs that have or have the power to request authority to set a UPL.<sup>12</sup></li><li>Three states (ME, NJ, OR) have PDABs that review the affordability of prescription drugs but do not have the authority to set a UPL.<sup>13</sup> In June 2025, the General Court of New Hampshire voted to dissolve the state's PDAB due to budget cuts.<sup>14</sup></li></ul>
17+	During the 2024 state legislative sessions, at least <b>seventeen</b> states were considering PDAB legislation. <sup>15</sup>
\$700,000	Colorado and Maryland, the two states furthest along in PDAB implementation, had initial start-up costs over <b>\$700,000</b> . <sup>16,17</sup>
3	Just <b>three</b> drugs have been deemed "unaffordable" following a PDAB review.
0	To date, there have been <b>zero</b> dollars worth of patient savings as a result of PDABs.

\*As of November 2025

<sup>1</sup> For this metric, states with "enacted PDAB legislation" includes only those states with PDABs or councils currently in place which review drugs purchased by both public and private insurers. This excludes New York and Massachusetts, both of which are engaged in affordability review initiatives focusing solely on drugs purchased by their corresponding Medicaid Agencies, and Vermont, which currently has a Board that is directed to study existing PDABs and develop a similar initiative in the state.

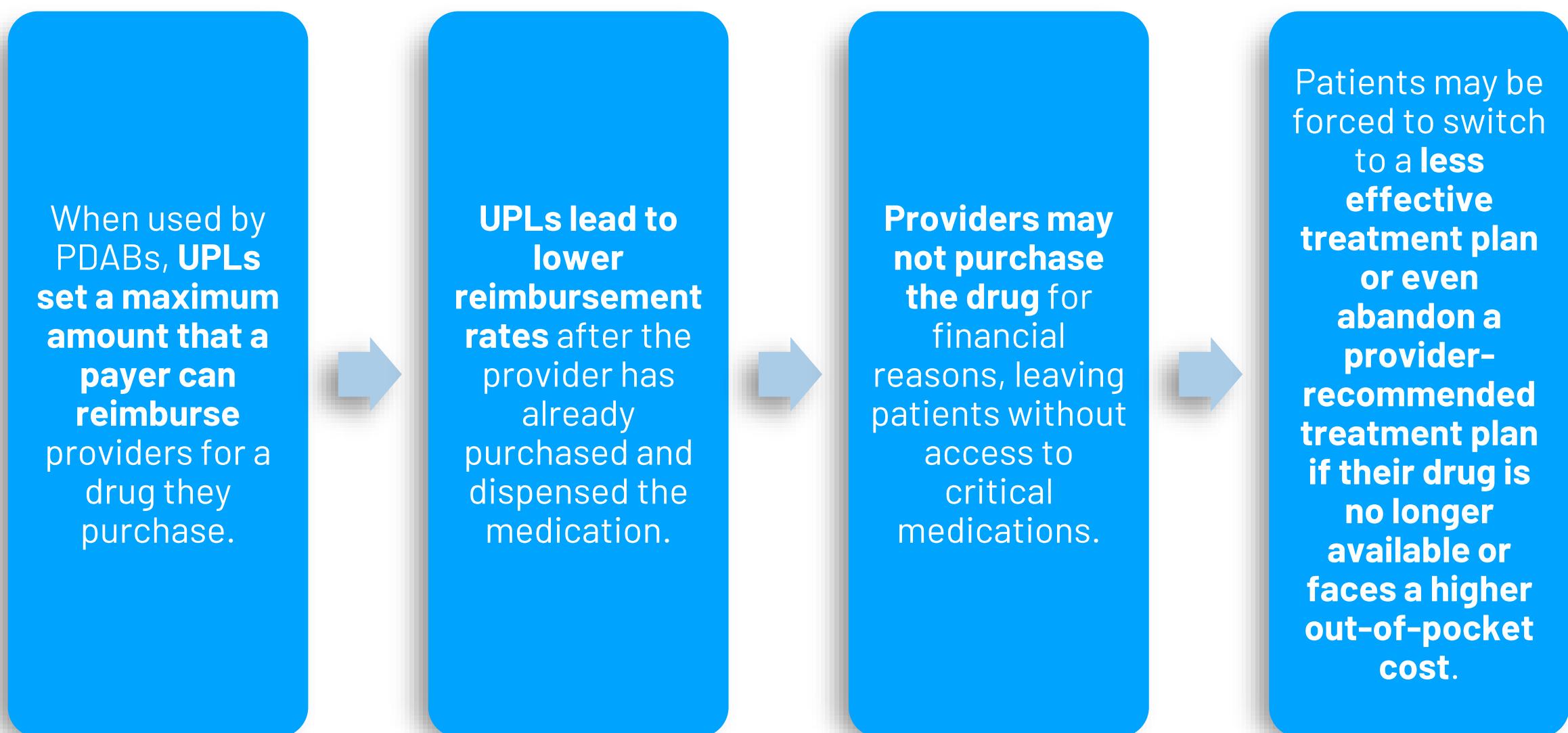
## Analysis and Impact of UPLs

The only tool many established PDABs have to lower the costs of medications is a UPL, which may harm the very patients PDABs were created to protect.

*"UPLs do not ultimately impact the bottom line at the pharmacy for patients."*

Desmond Banks, Policy Director, National Black Caucus of State Legislators (NBCSL)

UPLs do not impact the purchase price of a medicine; instead, they set a limit on the amount that a provider responsible for stocking, storing, and administering the medicine can reimburse for that treatment.<sup>18</sup> When providers, such as pharmacists, are faced with these lower reimbursement rates, they are forced to make difficult decisions – either prescribe a treatment that may not be their first-line recommendation for a patient to ensure reimbursement at the adequate rate or take a financial loss on a treatment that they know is preferred for their patient.<sup>19</sup>



**The National Alliance of State Pharmacy Associations (NASPA) identified five key risks incurred through the establishment of PDABs and UPLs in states, particularly as they relate to pharmacy reimbursement<sup>20</sup>. NASPA concerns include:**

- **Reduced reimbursement rates**
- **Impacts on pharmacy cash flow**
- **Increased administrative burden**
- **Impacts on patient care**
- **Incentives for generic substitutions**

With local and independent pharmacies serving as essential community hubs for healthcare resources and information, and frequently operating with thin profit margins, negative consequences as a result of UPLs threaten these institutions' continued ability to keep their doors open and provide care to the patients they serve.

These impacts extend to independent providers, such as clinical oncologists, dermatologists, and rheumatologists, who have expressed concerns about the potential consequences of UPLs. Such consequences, including lower reimbursement rates, stand to negatively impact providers' ability to pay staff, stock and administer critical treatments, and keep their doors open to provide care to their patients.<sup>21</sup>

A draft resolution introduced by the Association for Clinical Oncology, American Academy of Dermatology Association, American College of Mohs Surgery, American Contact Dermatitis Society, and the American College of Rheumatology in April 2024 calls for the American Medical Association (AMA) to conduct a study to determine how PDAB-enacted UPLs impact reimbursement for physician-administered drugs and patient access.

*“...state PDAB legislation that includes UPL authority often lacks language that would allow physicians to seek reimbursement for storage and handling of a physician-administered drug subject to a UPL.”<sup>22</sup>*

#### American Medical Association House of Delegates

*“It is not the role of the government, let alone a state government, to get involved in the list price of the drug. It’s just too complicated for a state to know everything about the ecosystem for a drug price.”*

**Carl Schmid, Executive Director, HIV+Hepatitis Policy Institute**

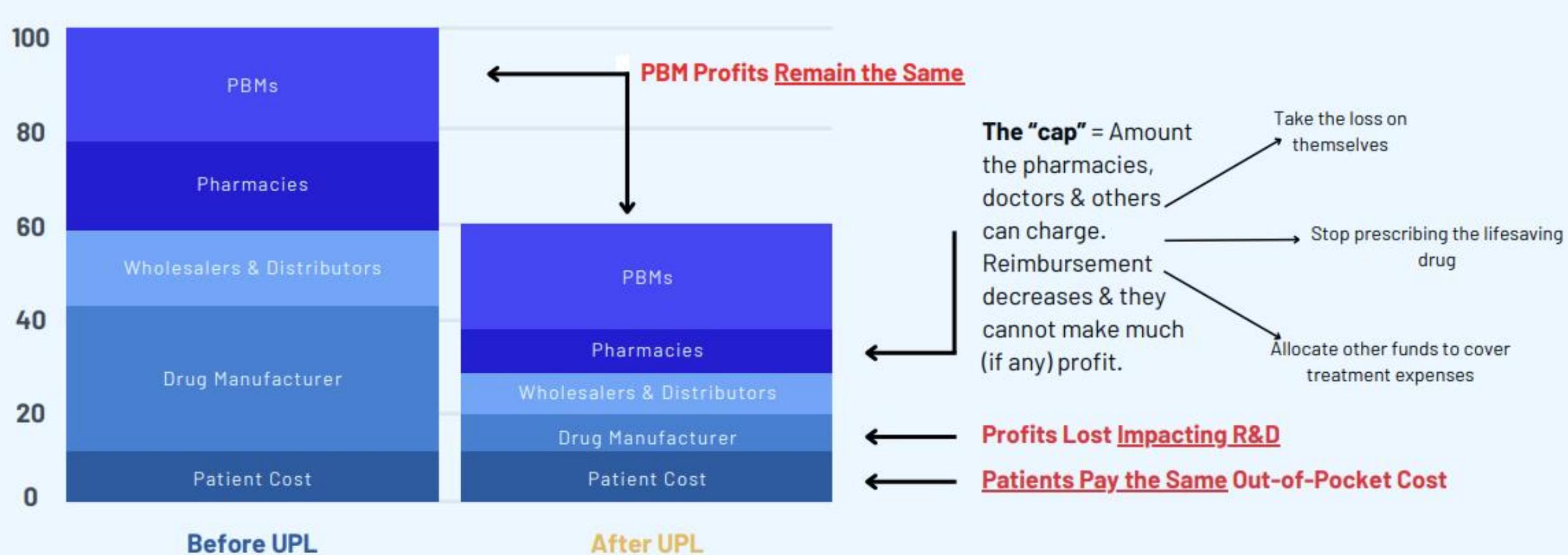
UPLs fail to address one of the significant drivers of healthcare costs – pharmacy benefit manager (PBM) practices. PBM profits are unaffected by UPLs. By placing caps on medication reimbursement rates, not only are patients not saving money at the pharmacy counter, but providers are forced to stop prescribing recommended treatments, and research and development efforts are negatively impacted.

## What is a Pharmacy Benefit Manager (PBM)?<sup>23</sup>

PBMs are third-party, for-profit entities that act as middlemen between pharmaceutical companies, payers (both public and private), and pharmacies. They have a direct impact on both drug prices and patient access because they both create and update formularies of preferred drugs, and negotiate the prices, rebates, and discounts from manufacturers while also determining the prices that insurers pay and reimbursement rates for pharmacies.

PBMs generate profit in three primary ways: through administrative fees paid by insurers for their services, by capturing some of the savings from the rebates they negotiate from drug manufacturers, and through spread pricing, where PBMs charge a higher payment from insurers for a drug than PBMs pay to pharmacies for the same drug. In the latter two cases, PBMs keep these differences as profit, driving up prices for patients at the pharmacy counter.

**Figure 1: PBM Mechanisms<sup>24</sup>**



## Impacts Across the Healthcare Ecosystem

The pharmaceutical supply chain—responsible for bringing treatments from the lab to patients—is a complex ecosystem that relies on alignment and cooperation between all players within it. If just one link in the healthcare supply chain, which spans from the initial discovery of treatment to patients, is impacted, patients will bear the brunt of those changes as the end users.

Both the model legislation that many states have enacted and new PDAB legislation under consideration empower the governor-appointed board members with the ultimate authority to determine access to treatments that patients rely on to stay healthy and alive. In several cases, patient advocates have voiced concerns about a lack of knowledge from boards about a specific treatment or therapeutic area. As these state boards make decisions that significantly impact patient lives and health outcomes, board members must be equipped with tools and knowledge informed by stakeholders across the supply chain to mitigate broader, system-wide impacts.

With zero evidence to suggest that implementing a UPL through a PDAB can lead to meaningful cost savings for patients—and research pointing to the contrary—states must consider additional methods to meaningfully lower patient costs.

*"Upper payment limits will never help the patient. The cost will only help the insurance companies. Savings are never going to reach the patient, and it will impact future research and development."*

**Laura Bonnell, President, The Bonnell Foundation**

*"In response to patients expressing concern that board decisions may impact our access to treatments, some of the PDABs expressed that this whole exercise is about affordability, not about patient access to treatments."*

**Tiffany Westrich-Robertson, Chief Executive Officer & Co-Founder, International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)**

Research from the Partnership to Fight Chronic Disease (PFCD) published in 2024 and 2025 explored payer perspectives on UPLs, which revealed the potential impacts of PDABs' use of these tools to set price limits on prescription medicines.<sup>25,26</sup>

- *77% of health plans believe UPLs will disrupt patient access to prescription drugs due to changes in coverage, tiering, cost sharing, or broader supply chain issues.*
- *Most surveyed payers (five of six) did not anticipate that UPL-related savings would be passed on to patients in the form of lower premiums, deductibles, or cost sharing.*
- *Payers expressed that UPLs may place unintended financial pressures on provider administered UPL drugs.*

*All payers interviewed noted that UPL drugs and competitors in the therapeutic class are likely to see increased utilization management should the UPL restructure new benefit designs.*

## The Case Against PDABs & UPLs

### Patient Access Implications

Patients, advocates, providers, industry members, and other stakeholders have come forward to share their perspectives and voice their concerns about the impact PDABs and UPLs could have on patients' ability to access and afford prescription medications. While on the surface, PDABs may sound promising for patients, they are often implemented in the name of politics under the guise of patient access.

There is an inequitable approach to addressing cost, given that affordability parameters vary by patient, region, disease state, and circumstance. Many PDABs do not define affordability or make clear the criteria they will use to determine whether or not a drug is affordable. This lack of clarity introduces significant risks to health equity, furthering the risk that where someone lives will determine their health status and access to medicines by creating greater variance state by state.<sup>27</sup>

*"PDABs raise several alarm bells when it comes to access. They're focused on one thing which is cost and often at the expense of access and innovation for patients."*

Derek Flowers, Executive Director, Value of Care Coalition

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*"Colorado has a really small cystic fibrosis (CF) community, but it is very vocal. There wasn't anyone on the Colorado PDAB who knew more than the CF community. However, that advocacy was challenging because not everyone on the Board was receptive. They didn't even speak to their rare disease advisory council until one of us suggested it."*

Laura Bonnell, President, The Bonnell Foundation

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Many patients have felt excluded by the PDAB process. PDABs largely lack patient representation and tend to be monolithic in other ways.<sup>28</sup> Further, opportunities for patient input are few and far between and are often communicated at the last minute – in some cases, only a few hours before a meeting. For many, participation is not feasible on such short notice, especially when the time allotted to a speaker can be as little as a couple of minutes.

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*"Through the Colorado PDAB process, we saw the power and the importance of patient advocacy. The CF community really galvanized and spoke up for themselves."*

Meredith Marden, Analyst, Community Health Programs and Public Policy, The Boomer Esiason Foundation

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*"PDABs are a buzzword solution that sounds like it will make prescription drugs less expensive. But really, we know when you pull up the hood and look at all the moving parts, they really threaten patient access near term, and innovation long term."*

Candace DeMatteis, Policy Director, Partnership to Fight Chronic Disease (PFCD)

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PDABs further threaten patient access through the threat of increased utilization management protocols and other practices implemented by PBMs and insurers. With these practices, like step therapy, a patient's provider-recommended course of treatment can be delayed. In contrast, the patient must first attempt cheaper therapies that must fail before a new regimen can be tried. Further, many metrics utilized in these practices and PDAB guidelines are discriminatory or misleading by design – such as value assessment frameworks (e.g., quality-adjusted life years (QALYs)) and international reference pricing.

## CASE STUDY: The Impact of PDABs & UPLs on Patients Living with Rare Diseases

For people living with rare diseases, the impact of PDABs and UPLs threaten to be especially dire. Rare diseases are those that affect less than 200,000 people in the U.S. It is estimated that there are up to 10,000 rare diseases that have been identified and, of these, only five percent of rare diseases have an FDA-approved treatment.<sup>29</sup> A white paper by the Rare Access Action Project (RAAP) outlines the impact of PDABs and UPLs on people living with rare diseases.<sup>30</sup>

*Patients with rare diseases may face formulary restrictions or utilization management – similar to patients with other conditions – but the lack of treatment options for rare diseases makes any impact on access particularly concerning.*

*Many states are permitted to use QALYs in affordability assessments which overlook individual patient needs and are viewed as discriminatory towards rare disease patients by devaluing the lives of patients living with chronic disease.*

*Other federal and state policies recognize the importance of ensuring access and continued innovation into orphan drugs and have excluded these treatments from price controls. PDABs have failed to make this distinction so far.*

*Due to the small patient populations, orphan drug manufacturers already take a risk to develop these treatments. PDABs, and other types of price controls, threaten to divert critical resources away from research and development of orphan drugs.*

**One in three cancer patients and caregivers reported experiencing treatment delays due to a provider being forced to wait for approval from an insurer for a medication or test as a result of a utilization management tactic known as prior authorization.<sup>31</sup>**

## Innovation Implications

*"Controlling healthcare costs is undeniably important... but fostering an environment that encourages the development of new treatments is equally vital."*

Scott Bertani, Director of Public Policy, HealthHIV

Beyond the more immediate impacts on patients, PDABs, and UPLs threaten to create negative consequences for medical innovation, which will have a downstream negative impact on patients looking to manage symptoms and live longer healthier lives.

If pharmaceutical companies cannot recoup the cost of their research and development, economics dictates that they will not be able to continue producing that drug and others. A successful drug that comes to market for a company does not only provide for the investment in its own development—it also provides for the many drugs that never make it to market and in which billions have been invested. This externality is not considered in most measures of a drug's profitability, and if it were included, this metric would likely lower substantially.

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The timeline to bring a drug from a test tube to the market can take 12 years and often much longer.<sup>32</sup>

*"I want people to have access to low-cost drugs, but if it impacts R&D, then you will have collateral damage, which equals loss of life. How do we get a solution where we both win – for the patient?"*

Maimah Karmo, Chief Executive Officer & Survivor, Tigerlily Foundation

*"It is so important for pharma companies to invest in rare diseases, and they're not going to if they can't make money. It is a business, making money isn't a bad thing. We can't hate pharma. We can't hate the insurance companies. We all have to work together."*

Laura Bonnell, President, The Bonnell Foundation

Recently, the CEOs of three large pharmaceutical companies testified in front of the United States Congress regarding drug pricing, where they spoke to the enormous costs of bringing a drug to market, **the average being more than \$2 billion.**<sup>33</sup> Additionally, while Americans may face higher drug prices than those in other countries, they enjoy faster and greater access to life-saving therapies.

*"Health innovation requires significant capital and a stable, predictable regulatory environment to bring patients new medicines. Investors want to do everything they can to avoid risk. The threat of UPLs creates substantial uncertainties and challenges, making it harder for companies to raise capital to conduct research and development for new medicines. Setting UPLs could have serious unintended consequences not only on patients' access to life-saving and life-changing medicines, but also on the feasibility of bringing new, innovative therapies to patients with unmet medical needs."*

Amy Goodman, Vice President and Counsel for Policy + Advocacy, Colorado Bioscience Association

If these companies cannot operate due to a risky financial environment, there will also be a disproportionate negative impact on rare disease research.

## Healthy Aging Implications

The impacts of PDABs and UPLs on access and incremental innovation threaten to directly impact patients' ability to age healthily and live longer lives.

The longevity we enjoy today is due in no small part to access to innovative treatments. Reduced access threatens healthy aging. By 2054, 84 million adults ages 65 and older will make up an estimated 23% of the U.S. population, many of whom will be living with at least one medical condition requiring intervention.<sup>35</sup>

The positive contributions that biotech and pharmaceutical companies have on local, state, and national economies is also often overlooked. Smaller biotechnology companies do much of the drug development for rare diseases, facing high start-up costs that must be financed privately, such as by venture capital.<sup>34</sup> It is only after a drug delivers promising results that a small company can attract more stable financing, meaning that this critical research area is highly risky for potential investors. This has a huge impact on smaller communities that are often buoyed by biotech start-ups – which bring jobs and positive economic contributions.

*"Advances in HIV medication have historically transformed the prognosis and quality of life for individuals living with HIV, and it turned a once fatal disease into a manageable condition with access. Continued progress in the field: It is essential for addressing emerging challenges. That is about drug resistance, coinfections, and the need for more accessible treatment. As we talk about upper payment limits, they significantly slow the pace of innovation, coming from a field that lies on continual advancements – I am a glowing example of that, living with HIV for 30 years. Without the treatments, I, too, would not be here."*

Scott Bertani, Director of Public Policy, HealthHIV

## **CASE STUDY: Implications of PDABs on Treatments for HIV & Unique Patient Population Needs**

To avoid instituting additional barriers to treatment and care, individual patient and caregiver experiences must be taken into account through meaningful engagement tailored to specific populations. The Colorado PDAB found that a reviewed treatment for HIV is not unaffordable, in part due to the **state, federal, and manufacturer-provided programs that make such treatments accessible and affordable to those who need them.**

A white paper from HealthHIV highlights the need for PDABs to meaningfully consider the unique needs of specific patient populations while examining the role of patient assistance programs, such as the 340B Drug Pricing Program, in linking patients with care – particularly as it relates to HIV.<sup>36</sup>

*“PDABs are meant to make prescription drugs cheaper, but their actual impact on what people pay in the real world can vary. This highlights the need to balance cost-cutting carefully, keeping healthcare choices open while supporting critical programs like 340B.”*

PDABs must ensure that their efforts do not negatively impact ongoing policies and programs that are making treatments, such as those for HIV, more accessible to those who rely on them to stay healthy and live longer.

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Community Access National Network (CANN) developed a resource to highlight the specific impacts of PDABs and UPLs on efforts to end the HIV epidemic in the United States.<sup>37</sup>

The 340B program was established by Congress in 1992 with the intention of enabling hospitals and clinics to provide care to low-income and uninsured patients.

### **CANN shed light on the impact of UPLs on providers and patients as it relates to 340B:**

- I. 340B's value is found in the "spread" between the reimbursement rates and a reduced acquisition cost by way of drug manufacturer 340B rebates
- II. Reducing reimbursement rates by way of an "upper payment limit" will reduce the value realized by 340B rebates
- III. Providers end up with less money, which means they can afford to fund less services

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If PDABs and UPLs lead to lower reimbursement rates for clinics that provide lower-cost care, they threaten access to critical HIV treatments for patients and the ability of these providers to keep their doors open. PDABs must ensure that their efforts do not negatively impact ongoing policies and programs that are making treatments, such as those for HIV, more accessible to those who rely on them to stay healthy and live longer.

## A Framework for Patient, Caregiver & Provider Engagement

In the states furthest along in implementing their PDAB—Colorado and Maryland—advocates and stakeholders have voiced concerns about a lack of transparency within the PDAB process and a lack of engagement from those who stand to be most impacted by such policies and decisions.

*"State PDABs and the implementation of UPLs do not account for the complexities of the intricate healthcare ecosystem that facilitates treatments from manufacturers to patients. One single state doesn't have the ability or insight beyond their own borders to bring together the data and input required to mitigate system-wide ripple effects that ultimately stand to negatively impact patients."*

India Peterson Valentine, Vice President of State Government Affairs, Gilead Sciences

In March 2024, the Board selected eight drugs for a cost review. However, unlike in other states, this process was not transparent, with the list of eligible drugs only being shared with Maryland Board members.<sup>38</sup> This left patients wondering whether a treatment they rely on to manage their health might be put out of reach.

The healthcare supply chain is incredibly complex and spans far beyond just one state's borders. In many cases, states lack the knowledge and ability to control for impacts throughout the supply chain, and the visibility to consider all relevant data regarding a specific treatment, given the various factors that impact this delicate process outside of one state. In an effort to better understand what affordability truly means, members of the Oregon PDAB unanimously voted during a June 2024 meeting to "pause" their work of selecting drugs for affordability reviews until 2025. The pause is intended to facilitate alignment around terms and processes central to their efforts, including data collection around the net prices of treatments and a definition of affordability.<sup>39</sup>

*"We need to keep working to establish a framework of patient engagement throughout the entire implementation and policy-making process."*

Maxine Miller, Coordinator of Policy & Advocacy, Cancer Support Community (CSC)

## A Case Study in Drug Selection

Consider the process in Maryland. In February 2024, the Maryland PDAB received an initial list of over 2,000 prescription drugs eligible for a cost review based on the Board's rules and regulations.

In 2025, the Ensuring Access Through Collaborative Health (EACH) and Patient Inclusion Council (PIC) two-part coalition published results of a patient-experience survey to determine drivers of patient unaffordability and to share those results for PDABs' consideration in an effort to inform patient engagement with PDABs going forward.<sup>40</sup> The survey findings concluded:

- All patients who stopped taking a medication due to affordability described insurance-related reasons, not personal financial strain.
- Patients using manufacturer copay assistance or patient assistance programs overwhelmingly reported that their medications were affordable.

Many patients reported financial burden due to the cumulative costs of managing a chronic condition rather than cost of one individual treatment.

*"Affordability isn't a price tag—it's a lived experience. When policymakers focus only on retail prices, they overlook the true experience of patients. We're calling for policies that address the full scope of what makes medication inaccessible for patients."*

– Tiffany Westrich-Robertson, EACH/PIC Coalition Founder<sup>41</sup>

## Barriers to Participation

Across states, patients and other concerned stakeholders have demonstrated that the onus is put on them to engage with the PDAB, with boards failing to recognize the time, administrative, and financial barriers that may hinder patients' ability to attend a meeting or develop remarks to submit to the board. PDABs and staff must empower patients and caregivers to bring forward their stories and voice any concerns or questions while also proactively and meaningfully engaging key stakeholder communities throughout each stage of the process to mitigate unintended consequences on treatment access.

*"How do we ensure patients are at the table? Even as I'm working on the PDAB issue, I am often the only patient in the room, and the only black patient in the room. So it is my job to bring this work to people who are on the ground, who are like me."*

**Maimah Karmo, Chief Executive Officer & Survivor, Tigerlily Foundation**

## Accessible Engagement

*"We have to understand how we prioritize within communities, within academia, and within research what their priorities and needs are. We are a very trusted voice in our community, and we are the voice of members of our community. We've established a number of community advisory boards and a community task force that go out and talk about what we need to inform people of, and various topics, that we make sure to connect to the existing healthcare system. Aligning ourselves with existing partnerships and existing organizations are very key strategies. It is imperative to sustain our efforts in those community settings and other academic institutions as well."*

**Maisha Standifer, Director, Health Policy, Satcher Health Leadership Institute, Morehouse School of Medicine**

Meaningful patient engagement with policies that impact their health outcomes and treatment access cannot be limited to a 90-second public comment period from a limited and homogenous group of patients. PDABs must ensure broader and more accessible engagement with the patient communities; their policies and price limits stand to impact most to mitigate severe consequences on efforts to advance health equity and healthy aging.

In some cases, PDABs consult with an advisory council made up on representatives from various stakeholder communities, sometimes including patients. However, these councils have little to no authority over the PDAB and in many cases, their recommendations to the board have been disregarded and rejected. There is missed opportunity to provide a more meaningful consultation to all stakeholders, including patients, families, and caregivers.

*"The only real way to make a difference is to build in and require engagement."*

**Sara Traigle van Geertruyden, Executive Director, Partnership to Improve Patient Care (PIPC)**

## Best Practices for Meaningful Engagement on State Drug Pricing Policy

- **Patients must be considered the experts on the treatments being considered and reviewed by any entity developing policy** to address affordability challenges while avoiding negative impacts on access. Patients can serve a critical role in educating these entities once meaningfully engaged and recognized throughout the process.
- **Any entity considering policy to set drug prices, including lawmakers, regulators, and PDABs, must carefully consider the short- and long-term impacts of setting price limits on medicines** to mitigate unintended consequences on patient health outcomes, healthy aging, and health equity.
- **Entities enacting state drug pricing policy cannot treat engagement surrounding each drug considered or selected for affordability review as a one-size-fits-all process.** For certain conditions, such as HIV, there continue to be intersectional impacts and stigma surrounding a diagnosis or treatment, which may create further barriers to engagement.
- **Every patient and caregiver has a unique perception of the value of any given treatment.** Considering what patients value in relation to their prescription medicine is critical as PDABs, lawmakers, regulators, and other entities review prescription drugs to determine affordability.
  - Examples of factors that influence this include the cost of treatment compared to the financial, administrative, and time burden of increased hospital visits, decreased ability to work, etc... due to a lack of access to treatment.
- **Data collected and considered as part of any price setting process must be comprehensive and relevant to the population impacted by any potential price-setting policy.** These entities can engage patients in the data collection by developing surveys to accurately and effectively capture patient perspectives and input and proactively empower patients to participate in the survey.

- **Patients are willing to engage with entities that are reviewing and establishing drug prices throughout the implementation and processes.** By engaging patients in meaningful and ongoing ways, these entities can work to reduce the risk of adverse consequences on access in the long term.
- **The impact on treatments for rare diseases must be taken into account by any entity creating policies that will impact access to care,** given the small size of the patient population that treatments for rare or orphan conditions serve and the unique structure of patient assistance programs for those medicines.

**KEY TAKEAWAY:** *Policymakers interested in reducing out of pocket costs for patients must consider the negative impacts in policy decision making. Furthermore, incorporating diverse patient voices and perspectives into the price setting engagement process and establishing an ongoing feedback loop surrounding the reviews of any specific prescription medication is essential to mitigate unintended impacts on patients and other disruptions to the complex pharmaceutical supply chain.*

## Compounding Impacts of Federal & State Price Controls

### Inflation Reduction Act Medicare Drug Price Negotiation Program

The intersection of state and federal drug pricing policies threatens to further negatively impact patient access to necessary treatments. At the federal level, the Inflation Reduction Act of 2022 (IRA) empowers Medicare to negotiate drug prices directly with pharmaceutical manufacturers through the establishment of the Medicare Drug Price Negotiation Program (MDPBP). While there are provisions within the IRA that will help support patients in accessing the treatments they need, Medicare price negotiations will restrict access to life-saving treatment options and create a chilling effect on drug research and discovery.

Through the MDPBP, the Centers for Medicare & Medicaid Services (CMS) selects drugs to undergo Medicare negotiations and sets a "Maximum Fair Price" – or MFP – that Medicare will pay for that drug. There are concerns that setting MFPs on medicines will lower the reimbursement rates for these treatments and negatively impact patients' ability to access their treatments.

In January 2025, the National Community Pharmacists Association (NCPA) published a survey of independent pharmacy owners and managers about the MDPBP.<sup>42</sup> The survey found:

**60.4** percent of independent pharmacists are considering not stocking one or more of the first 10 drugs part of the MDPBP.

**32.8** percent of independent pharmacists have already decided not to stock one or more of the first 10 drugs part of the MDPBP.

Independent pharmacies are critical for ensuring access for older populations and rural communities. More than half of pharmacists work in a community-based setting and 77 percent of community pharmacies serve populations of 50,000 people and fewer.<sup>43</sup> **Over 15 million Americans rely on independent pharmacies for optimal access to prescription medications** and those individuals are more likely to live in rural areas, be sixty-five years or older, and belong to low-income households.<sup>44</sup>

### Small Molecule vs Large Molecule Distinction

Additionally, as outlined by a GCOA policy brief published in June 2025, the IRA includes an arbitrary distinction between small and large molecule medicines which will disincentivize investment into discovering new small molecule drugs and impact patient access.<sup>45</sup>

Under the IRA, small molecule drugs, typically taken in pill, syrup, or inhaled form, will become subject to negotiated prices nine years after approval from the Food & Drug Administration (FDA). In contrast, large molecule biologic drugs, most often injected or infused in a doctor's office or hospital setting, are subject to negotiated prices 13 years after FDA approval. For patient populations who rely on small molecule drugs to manage their daily symptoms, such as older adults, rural communities, and those impacted by chronic conditions, limited access to existing treatments and a decrease in future drug discovery of these treatments can have significant adverse health impacts on these populations.

During the 2025 legislation session, some states introduced legislation that sought to establish reimbursement caps on prescription drugs using the Medicare MFPs. By referencing federally-set MFPs for state reimbursement caps, states are importing a pricing scheme specifically geared towards Medicare beneficiaries across the country and is not reflective of specific patient populations for individual states.

## Most-Favored-Nation

In May 2025, President Donald Trump signed an executive order titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients."<sup>47</sup> The executive order directed the Department of Health and Human Services (HHS) to establish most-favored-nation (MFN) price targets with pharmaceutical manufacturers.

The MFN price represents the lowest price paid by any country part of the Organization for Economic Cooperation and Development (OECD). Efforts to implement price controls at the federal and state level will negatively impact patients. States should not be importing federal drug pricing policies that threaten to limit patient access to essential medicines, stunt future drug development efforts, and harm aging communities.

## Conclusion

Existing PDABs and states across the country that are considering the establishment of such boards and other entities that would set the price of prescription medicines must consider the broader consequences on patient access, innovation, and healthy aging before advancing any such efforts. Further, existing PDABs must provide transparency into the affordability review process, methodologies used, and any implementation of UPLs to ensure patient and other stakeholder concerns about access and innovation are carefully considered and addressed.

By meaningfully engaging patients and other impacted stakeholders – and heeding their concerns – around decision-making processes and the use of UPLs or other price-setting mechanisms, these entities can mitigate widespread short and long-term negative consequences on access and affordability in their state and beyond for prescription drugs that are proven to support the health and well-being of vulnerable communities and healthy aging.

Additionally, an increasing number of states are adopting drug price-setting policies that bypass Prescription Drug Affordability Board (PDAB) review, removing the opportunity for meaningful input from patients and providers. Although these policies still rely on setting upper payment limits, they pose the same challenges to patient access and risk undermining transparency and stakeholder engagement in the affordability review process.

The growing body of evidence on PDABs, alarms from diverse patient communities, and processes that have played out in states with such boards demonstrates the significant risk that PDABs pose and why the patient voice must always be front and center in decisions that impact treatment access and health equity.

## Appendix

This brief was updated in November 2025 to reflect changes to the policy environment. The original policy brief was published in October 2024 following an expert roundtable discussion hosted on June 6, 2024, by the Global Coalition on Aging (GCOA)<sup>48</sup> entitled "The Risks of PDABs and Importance of Innovation for Healthy Aging and Health Equity." The roundtable brought together cross-sectoral experts who represent patients, caregivers, academia, biopharmaceutical innovators, and business communities to discuss PDABs, UPLs, and the risk they pose to the innovation that is needed to safeguard healthy aging and improve health equity.

This brief builds on two previous GCOA Alliance for Health Innovation policy briefs—the first from June 2023 on healthy aging and innovation and the second from September 2023 on the intersection of healthy aging, innovation, and oncology.

This policy brief was generated by the Global Coalition on Aging and highlights participant insights from the roundtable discussion. The brief is intended to raise awareness of the unintended consequences of PDABs and provide policy recommendations to ensure healthy aging for all. The comments and quotes made by participants contained throughout this brief may not represent the views of the entire group.

## Roundtable Participants<sup>II</sup>

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- **Adina Lasser**, Public Policy Manager, Alliance for Aging Research
- **Laura Bonnell**, President, The Bonnell Foundation
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- **Maxine Miller**, Coordinator of Policy & Advocacy, Cancer Support Community (CSC)
- **Amy Goodman**, Vice President and Counsel for Policy + Advocacy, Colorado BioScience Association
- **Carl Schmid**, Executive Director, HIV+Hepatitis Policy Institute
- **India Peterson Valentine**, Vice President of State Government Affairs, Gilead Sciences
- **Melissa Mitchell**, Executive Director, Global Coalition on Aging (GCOA)
- **Scott Bertani**, Director of Public Policy, HealthHIV
- **Desmond Banks**, Policy Director, National Black Caucus of State Legislators (NBCSL)
- **Gretchen C. Wartman**, Vice President for Policy and Program, National Minority Quality Forum (NMQF)
- **Candace DeMatteis**, Policy Director, Partnership to Fight Chronic Disease (PFCD)
- **Sara Traigle van Geertruyden**, Executive Director, Partnership to Improve Patient Care (PIPC)
- **Maisha Standifer**, Director, Health Policy, Satcher Health Leadership Institute, Morehouse School of Medicine
- **Maimah Karmo**, Chief Executive Officer & Survivor, Tigerlily Foundation
- **Derek Flowers**, Executive Director, Value of Care Coalition

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