Maryland

Comments PDAB -PDAB- <comments.pdab@maryland.gov>

UPL Comments

1 message

Sherita Golden [redacted] Wed, Aug 21, 2024 at 4:50 PM
To: "comments.pdab@maryland.gov" <comments.pdab@maryland.gov>

Good afternoon. I am a member of the Maryland Prescription Drug Accountability Board Stakeholder Council. I have reviewed the UPL document and have the following comments:

- One point of clarification in the document that would be helpful for me is to understand why products on the drug shortage list are excluded. Prices can really rise when there is a drug shortage so it is unclear to me why they would be excluded. It may be apparent and intuitive to those more familiar with the pharmaceutical supply chain but a brief statement in the document explaining why would be helpful for those who are not.
- I appreciate that the Board will utilize a cost-effectiveness analysis approach to be able to examine the costs of using each drug to treat a variety of disease processes, which will help standardize comparisons to some extent. The cost-effectiveness threshold will also vary for different drugs. This process makes sense to me but I am still not clear about the exact metrics being used to determine affordability challenges. Will the Board use an absolute cost to the state healthcare system or out of pocket threshold to determine high cost and set the UPL or will high cost be determined based on a proportion (e.g. XX% of the state healthcare system budget)?

The theoretical aspects are described; at the same time it would be helpful to understand how the final metrics will be determined.

Dr. Sherita Golden

Sherita Hill Golden, MD, MHS (she/her/hers)

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[redacted]

“Let your work speak for you…and you’ll never have to say anything about yourself.”

- Dr. Levi Watkins, Jr.

[redacted]

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Via Electronic Submission

August 19, 2024

Lorraine Diana, CRNP
Co-Chair
Maryland Prescription Drug Affordability Stakeholder Council

Marc Nicole
Co-Chair
Maryland Prescription Drug Affordability Stakeholder Council
comments.pdab@maryland.gov

Dear Co-Chairs Diana and Nicole:

We write to provide the Maryland Prescription Drug Affordability Stakeholder Council (the Stakeholder Council) with information on Johnson & Johnson's recent white paper, "Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem" (the UPL White Paper) in advance of the August 26, 2024 meeting.

At Johnson & Johnson, for more than 130 years, cutting-edge technologies and expert insight have helped us understand and address the serious health problems of today and unlock the potential medicines of tomorrow. We apply rigorous science and compassion to confidently address the most complex diseases of our time. We also recognize these medicines can only have an impact if patients can access them. We work tirelessly to improve access for patients across Maryland.

During the July 22, 2024 meeting, the Maryland Prescription Drug Affordability Board (PDAB) discussed the development of its Upper Payment Limit (UPL) Action Plan. As the Board and Stakeholder Council continue to shape the UPL Action Plan, J&J cautions that a UPL could negatively impact patient affordability and access. We have attached a copy of the UPL White Paper and would like to highlight the following points:

- **An upper payment limit (UPL) will not lower patients' out-of-pocket costs.**[1] In a recent Avalere survey commissioned by the Partnership to Fight Chronic Disease, health plans stated "[p]ayers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences."[2]
- **A UPL will negatively impact patient access.**[1] In the same Avalere survey, health plans stated "[u]tilization management will undoubtedly go up with UPLs, whether for the

[1] Janssen. "Influence of Prescription Drug Affordability Board and Upper Payment Limits on the State Drug Pricing Ecosystem." Access July 3, 2024.

drugs subjected to them or for competition."[2]

- **A UPL does not consider the drug supply chain in its entirety.**[1] A UPL does not consider the role that health plans and pharmacy benefit managers play in the supply chain, nor does it consider the negative impact on provider and pharmacy reimbursement, which may result in providers and pharmacies operating at a loss.[3]

Instead of a UPL, we recommend the following policy solutions to reduce patients' out-of-pocket costs without negatively impacting their access to the most appropriate, effective treatment options and sites of care:

- **Require that PBM rebates and discounts be directly shared with patients at the pharmacy counter.**[4]
- **Examine the use of utilization management tools (e.g., formulary exclusion lists, prior authorization, step therapy, and nonmedical switching) and evaluate how best to regulate them in the interest of patient access and out-of-pocket costs.**[4]
- **Prohibit diversion of cost-sharing assistance (i.e., copay accumulator programs, maximizer programs, and alternative funding programs) to ensure payment made by or on behalf of patients counts towards their cost-sharing burden.**[5]

We ask the Stakeholder Council to take these points and others made in the UPL White Paper into consideration as you move forward with your recommendations on the UPL process.

As one of the nation's leading healthcare companies, Johnson & Johnson has a responsibility to engage with stakeholders in constructive dialogue to address these gaps in affordability, access and health equity as well as protect our nation's leading role in the global innovation ecosystem.

We know that patients are counting on us to develop medicines and work to make them accessible to all patients. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives.

Sincerely,

Judy Jenkins, RN, BSN, MS
Director, U.S. State Government Affairs

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[2] Partnership to Fight Chronic Disease. "Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies and Benefit Design But Won't Reduce Patient Costs." Accessed July 3, 2024.
[3] Health Affairs. "Unanswered Questions and Unintended Consequences of State Prescription Drug Affordability Boards." Accessed June 5, 2024.
[4] Janssen. "The 2021 Janssen U.S. Pricing Transparency Brief." Accessed July 3, 2024.
[5] Janssen. "The 2022 Janssen U.S. Pricing Transparency Brief." Accessed July 3, 2024.

Influence of Prescription Drug Affordability Boards and Upper Payment Limits on the State Drug Pricing Ecosystem

Image Info: Microscopic Biology.

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Abstract & Executive Summary

Abstract

State policymakers are turning to prescription drug affordability boards (PDABs) and upper payment limits (UPLs) on branded medications to lower state drug expenditures and improve affordability for patients. However, UPLs on branded medications remain new and untested, with minimal understanding of their short- and long-term impacts on the drug pricing ecosystem and patient access. As presented, UPLs may offer states a short-term option for reducing overall drug spending for the state.

However, because UPLs focus solely on the price of a drug instead of the entire drug supply chain ecosystem, they may have long-term negative impacts across benefit design, patient access, pricing, contracting and future innovation.

These impacts may prohibit states from achieving their intended effects across state-regulated commercial markets and, in fact, create new negative consequences, including reduced patient access to needed medications and little to no reduction of out-of-pocket costs for patients. States seeking to implement UPLs on branded medications should consider the downstream consequences of focusing on drug price setting, specifically for patients and providers.

Executive Summary

Over the past 10 years, stakeholders have increased their focus on the rising cost of healthcare, in particular drug pricing, patient access and affordability. Manufacturers, insurers and pharmacy benefit managers (PBMs) have been the primary focus of scrutiny. In response, **legislators have passed laws designed to curb government prescription drug spending, improve patient accessibility and affordability and increase transparency in the pricing process at both federal and state levels.**

The passage of the Inflation Reduction Act (IRA) in August 2022 has further prompted states to act against perceived rises in drug prices and spending. States have turned to prescription drug affordability boards (PDABs) and new price-setting measures such as upper payment limits (UPLs) for branded medications in hopes of reducing overall state drug spending and patient drug costs. Upper payment limits are not new in policymaking: for example, the Federal Upper Limit sets a reimbursement limit for some generic drugs. However, UPLs have not been used on branded medications where the manufacturer and the plans currently negotiate value and access. These new UPLs purportedly allow states to set limits on the amount that will be reimbursed for specified branded drugs across state-regulated commercial markets. More than 10 state legislatures have debated price-setting thresholds such as UPLs in the last legislative session. As of November 2023, no state has fully implemented a UPL; however, Colorado is finalizing UPL rulemaking and may choose to implement UPLs in 2024.

UPLs on branded medications may have unintended consequences for stakeholders, pricing and value via altered benefit designs, manufacturer contracting, provider incentives, patient access and future innovation. Further, as additional state legislatures debate the merits of PDABs and these new applications of UPLs on branded medications, there is limited research to understand the long-term consequences of such policies.

This paper aims to address potential intended and unintended consequences of PDAB and UPL implementation on branded medications for states and the broader healthcare ecosystem.

The Initial Development of PDABs and UPLs

Early Attempts to Address Drug Pricing in the States

National healthcare expenditures have grown substantially, increasing from **$74.1 billion** in 1970 to **$4.3 trillion** in 2021.[1]

While much of this increase is due to hospital expenditures, a growing percentage is due to higher prescription drug expenditures, attributable to increases in both volume and costs. While the absolute cost of drug spending has grown, it has maintained a stable percentage of **overall healthcare spending at 14 percent** for several years.[2]

As such, lowering drug costs and improving patient affordability have been priorities for state lawmakers for many years. However, since the passage of the Patient Protection and Affordable Care Act (ACA) and the expansion of the individual market through state marketplaces, legislation targeting drug expenditures has multiplied.[3]

Prior to the development of PDABs and UPLs, states debated several other legislative and regulatory efforts, including increasing manufacturer price transparency within the commercial prescription drug supply chain. Drug price transparency legislation, which included manufacturer reporting requirements and advance notification of price changes (e.g., drugs with a wholesale acquisition cost [WAC] increase greater than 10 percent over the previous 12 months), rose to the forefront of state legislative initiatives around 2016. At least 24 states have enacted such laws.

However, state drug price transparency laws have not reduced prescription drug costs and improved transparency in the way states intended.[4] Research indicates that price transparency alone has minimal impact on overall costs for consumers because the information reported under transparency laws does not typically lead to actionable reductions in drug prices and reduced prices do not necessarily result in cost savings for patients.[5]

In addition to early drug price transparency legislation, some states also sought price-capping initiatives in the commercial market and in Medicaid. For example, New York's Medicaid Drug Spending Cap was enacted in 2017, allowing the state Medicaid program to negotiate with manufacturers for supplemental rebates if spending was set to exceed the cap or if a new drug was launched with a "high cost."[6] Maryland enacted an anti-price gouging law in 2017 that intended to penalize manufacturers for unreasonably increasing the cost of drugs.[7,8] However, a Court of Appeals struck down the Maryland law the following year stating it violated the commerce clause by regulating transactions taking place outside the state.[9] After the court decision, states began considering PDABs and price setting as a way to reduce prescription drug prices without negotiations with manufacturers.

PDAB and UPL Development

1

Background

PDABs are established through state legislation to independently review state drug spend and recommend ways to lower spending.[10] In 2017, the National Academy for State Health Policy (NASHP) developed model PDAB legislative language including a definition of prescription drug price setting through UPLs. This language was designed to give PDABs the ability to determine, using a UPL framework, if a drug is "unaffordable" for state purchasers and consumers.[6] The intent of the original model bill was to bring different stakeholders of the prescription drug pricing process together to increase transparency and set price thresholds to limit how much the state would pay for identified drugs.[11]

The original framework encouraged Boards to consider factors such as:

- Cost of administering and delivering the drug,
- Food and Drug Administration (FDA) shortage list status,
- Price of the drug in other countries and
- Other relevant administrative costs.

The framework does not require, however, that the value of the drug or the patient benefits be considered when determining a UPL.[12]

Even more notably, the NASHP model bill does not explicitly address patient cost sharing or affordability as a factor, although states are able to include it if they deem it necessary. NASHP updated the model legislation in 2022 to tie UPLs to reference-based pricing such as Medicare "negotiated rates" as developed by the IRA.[13] To date, UPLs have been designed as a cost-saving measure for the state and the plans that work within the state and have not been assessed as a mechanism to directly reduce out-of-pocket costs for patients.

2

PDAB Development

Maryland enacted the first PDAB in 2019 followed by Maine, New Hampshire, Oregon, Ohio, Colorado and Washington.[14] The scope of these PDABs varies from state to state. The majority of PDABs include advisory boards to analyze and recommend ways to lower state spending on certain products; others are required to release reports on their analyses or findings. In March 2022, Maine's PDAB released its first annual report containing administrative and legislative recommendations on how to reduce prescription drug prices in the state.[15]

While the composition of PDABs varies by state, most boards are composed of state-appointed experts in various fields of healthcare and economics. Many states' PDABs also include other stakeholders such as healthcare providers, advocates, manufacturers and insurance professionals.[10] The varied backgrounds of PDAB members can lead to differentiation in selection criteria for affordability review execution. Based on their individual areas of expertise, certain members may value utilization while others may value health equity.

PDABs often focus on branded drugs with list prices and use across state-regulated plans, using standard thresholds such as price and volume, to identify which drugs will be evaluated. For example, PDABs in Colorado and Maryland seek to evaluate drugs with a WAC greater than $30,000 per year. Ohio and Maine developed PDABs solely as ways to report to state legislatures on future drug pricing initiatives and ways states could engage with the supply chain to lower costs.[16, 17] However, some PDABs have the purported authority to set UPLs for select drugs.[14, 18]

States also need to provide funding for Boards to maintain their functionality. Some states have appropriated funds from the state budget for their PDAB, such as Washington's $1,460,000 allocation for the 2023 fiscal year.[19] Other states, like New Hampshire, fund their Boards through fees collected from manufacturers, insurers and PBMs.[14] Most states are still working to operationalize their Boards, with only Colorado, Maine and Maryland having active Boards as of July 2023.

3

UPL Development

Of the eight enacted PDAB laws, the following contain UPL price limit threshold provisions: Washington, Colorado, Minnesota and Maryland.[14] The goal of establishing UPLs is to set rates that state purchasers will pay for a certain number of products across plans regulated by the state (e.g., individual market, small-group market). States may include Medicaid plans as part of their state purchasers; however, Medicaid rates are likely already more steeply discounted than a UPL rate due to rebates through the Medicaid Drug Rebate Program (MDRP). So far, Minnesota is the only state to directly tie UPLs to Medicare "maximum fair price" (MFP) decisions developed through the IRA, although rulemaking to formalize this process has not been established.[20]

Other states with the authority to set UPLs have initiated their own criteria and processes for affordability review. Some states have thresholds on the number of drugs for which a UPL can be established. Currently enacted UPLs require states to determine the UPL-setting process through rulemaking considered by the PDAB.[14] PDAB laws with UPLs do not impact Employee Retirement Income Security Act of 1974 (ERISA) self-funded and Medicare plans.[10] However, these plans may opt into UPLs if enacted language allows. While price caps do exist in other markets, this has largely been untested in the state-regulated plans; as such, the impact of PDABs and UPLs on branded products is unclear.

PDAB and UPL Development Timeline

- Maryland enacted the first PDAB in 2019, followed by Maine, New Hampshire, Oregon, Ohio, Colorado and Washington.
- Many states' PDABs also include other stakeholders such as healthcare providers, advocates, manufacturers and insurance professionals.
- PDABs in Colorado and Maryland seek to evaluate drugs with a WAC greater than $30,000 per year.
- Ohio and Maine developed PDABs solely as ways to report to state legislatures on future drug pricing initiatives and ways states could engage with the supply chain to lower costs.
- States also need to provide funding for Boards to maintain their functionality.
- Some states have appropriated funds from the state budget for their PDAB, such as Washington's $1,460,000 allocation for the 2023 fiscal year.
- New Hampshire funds their Boards through fees collected from manufacturers, insurers and PBMs.
- Most states are still working to operationalize their Boards, with only Colorado, Maine and Maryland having active Boards as of July 2023.
- Of the eight enacted PDAB laws, the following contain UPL price limit threshold provisions: Washington, Colorado, Minnesota and Maryland.
- So far, Minnesota is the only state to directly tie UPLs to Medicare maximum fair price (MFP) decisions developed through the IRA, although rulemaking to formalize this process has not been established.

Current State of Play and UPL Implementation

PDAB/UPL Development in Three Key States

Three states with established PDABs are working toward developing a UPL setting process, with Colorado being the furthest along and in the process of finalizing rulemaking for its UPL.[10] The Colorado PDAB has released a list of five prioritized drugs for affordability review, following the release of a dashboard that includes 604 eligible drugs for selection.[21]

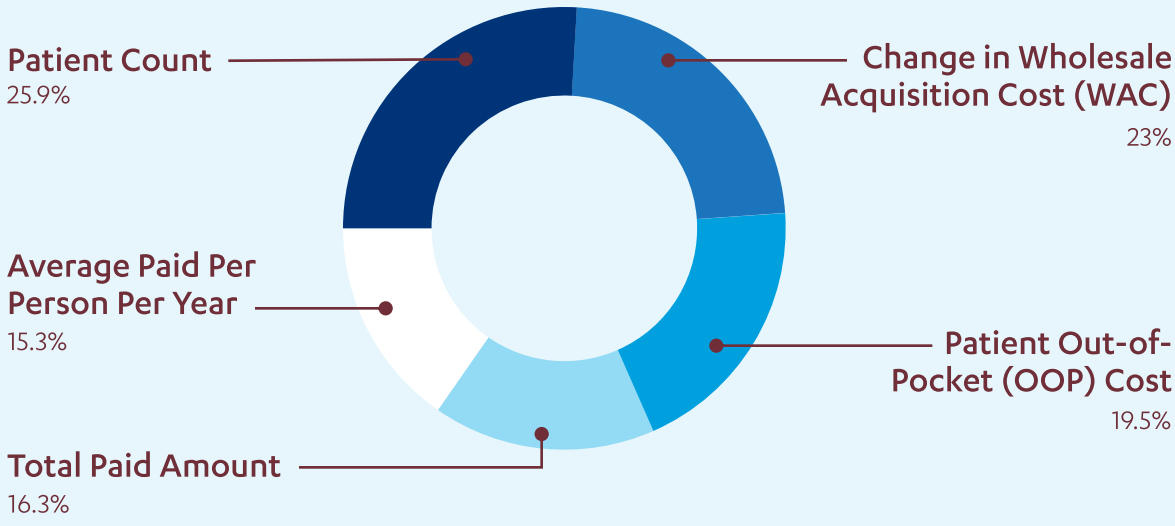
The 5 drugs selected for affordability review were:

1. Enbrel
2. Genvoya
3. Cosentyx
4. Stelara
5. Trikafta[22]

The Colorado PDAB plans to move forward with affordability reviews for the five selected drugs and may set UPLs for some, none or all of them, although the Board has the authority to set UPLs for up to 18 drugs (the CO PDAB has already announced it will not set an UPL for Trikafta).[23] The first UPLs in Colorado could take effect as early as 2024.

Each state's PDAB and UPL setting process and authorization can vary across items such as covered markets and targeted drugs. Maryland and Washington are two other states that have enacted PDABs. As a part of its 2021 legislative session, Maryland initiated the ability to include UPLs as part of its PDAB. Legislation that reestablishes this requirement and develops a plan of action to implement UPLs was enacted in the state's 2023 legislative session.[24, 25] Washington is one of the most recent states to enact a PDAB law that allows UPL setting. The Washington PDAB may set UPLs for up to 12 drugs beginning in 2027 and will begin identifying drugs to conduct affordability reviews by June 2023.[26] Though other states have enacted PDABs with abilities to set UPLs (i.e., Minnesota), Colorado, Maryland and Washington are the states that have begun taking steps to develop plans.

Factors Used to Determine the Priorities List of Eligible Drugs in Colorado Included:



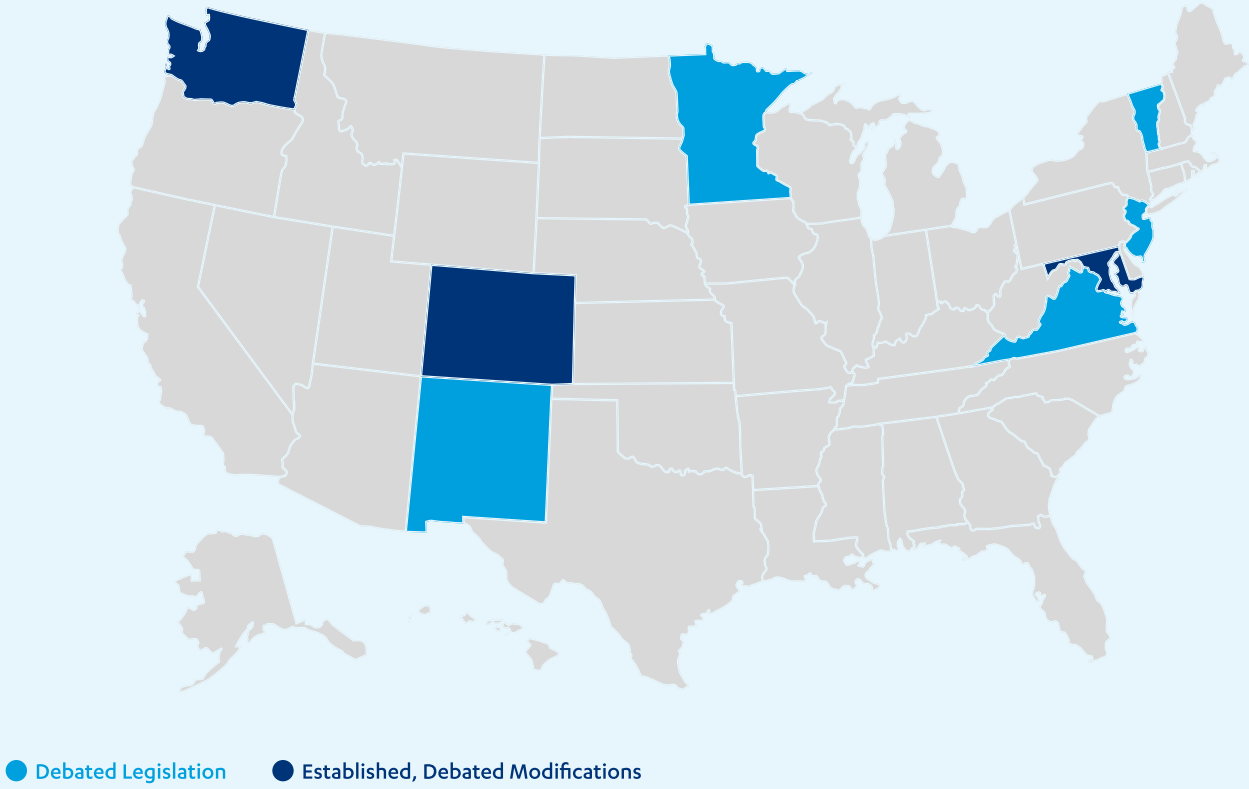
Key Characteristics of PDABs Across Three Enacted State Laws

	Colorado	Maryland	Washington
Bill Number	Colorado SB 175	Maryland HB 768	Washington SB 5532
Date Enacted	June 16, 2021	May 25, 2019	March 22, 2022
UPL Authorization	**Authorized.** The Colorado PDAB can set UPLs for up to 12 drugs within the first three years of implementation.[27]	**Progress toward authorization.** As a part of its 2021 legislative session, Maryland initiated the ability to include UPLs as part of its PDAB. However, no UPLs were set. HB 279 in Maryland's 2023 state legislative session gave the PDAB authority to set UPLs. If a UPL is established, the Maryland PDAB must report on UPL setting and the expansion of the UPL to other payers by December 1, 2026.[24]	**Authorized.** The Washington PDAB may set UPLs for up to 12 drugs, starting in 2027. A current bill seeks to move the Washington UPL ability forward by a year to 2026 as well as lower the thresholds for affordability review (e.g., WAC changes).[26]
Markets Covered	All state-regulated markets. This excludes self-funded plans that choose not to participate.	All public plans in the state.	All state-regulated markets. This excludes self-funded plans that choose not to participate
PDAB Drug Evaluation Criteria	• Brand-name drugs and biologics with a WAC ≥ $30,000 per year or course of treatment • Brand-name drugs or biologics with a WAC increase ≥ 10% during the previous 12 months • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[28]	• Brand-name drugs and biologics with a WAC ≥ $30,000 per year or course of treatment • Brand-name drugs with a price increase ≥ $3,000 in a year or course of treatment • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[29]	Prescription drugs that have been on the market for at least seven years, are not designated as rare disease treatments by the FDA and are one of the following: • Brand-name drugs and biologics with a WAC ≥ $60,000 per year or course of treatment • Brand-name drugs and biologics with a WAC increase ≥ 15% in a year • Brand-name drugs and biologics with a WAC increase ≥ 50% in three years • Biosimilars with a launch WAC that is not ≤ 15% lower than the referenced biologic • Generic drugs with a WAC ≥ $100 for a 30-day supply • Generic drugs with a WAC increase ≥ 200% in the previous 12 months[30]

To date, only Colorado has released a list of drugs selected for affordability review and possible UPL. However, Maryland notes in its annual cost review report that when the PDAB drug evaluation criteria are applied to their all-payer claims data (APCD), 707 brand-name national drug codes (NDCs) with WAC of over $30,000, 884 brand-name NDCs with increases of over $3,000, two NDCs of biosimilars not at least 15% less than the reference biologic and 483 NDCs of generic drugs costing $100 or more for a 30-day supply would be eligible for this review.[31]

Ongoing Legislative Efforts and IRA Implementation

In 2023 legislative sessions, at least five states have debated legislation to establish PDABs and UPLs (Minnesota, New Jersey, New Mexico, Vermont and Virginia) with Minnesota enacting its PDAB law in April 2023. All states with laws establishing PDABs with UPL authority prior to 2023 (Colorado, Maryland and Washington) have debated modifications to the process in their 2023 state legislative sessions.[32]



Beyond state legislation, Congress enacted major drug pricing reform through the IRA in August 2022.[33] The IRA's Medicare "negotiation" provision targets high-spend drugs, which could have downstream impacts on state PDAB and UPL development. For example, under Medicare "negotiation," a list of eligible drugs was released in September 2023 and the Secretary of the Department of Health and Human Services (HHS) will negotiate a "maximum fair price" (MFP) for each of the selected drugs to be effective in 2026.[34]

The MFP for each selected drug could impact UPL setting in states that enact laws tying UPLs to Medicare-negotiated rates. While federal "negotiation" is specific to Medicare, price-setting at the national level could trickle down to affect drug prices in state-regulated markets, and it can be expected that other states, like Minnesota, will tie the MFP to UPLs.

Affordability Ecosystem and Future Outlook for State Drug Pricing

Intended Outcomes of UPL Setting

1 Reduction in State Spending on Prescription Drugs

The goal of UPL setting is to establish payment limits for certain products to protect payers from high drug prices in the state and increase drug affordability for patients.

However, in states such as Colorado and Washington, where UPLs are limited to 12 products per year for the first three years, states may see nominal savings only if the products selected are tied to large enough state spending and volume.

Colorado's and Washington's laws purport to allow the PDABs to set no more than 12 UPLs a year until 2027, after which an unrestricted number of UPLs may be set. Early (e.g., pre-2027) savings from UPLs could mirror those projected by the Congressional Budget Office (CBO) for the IRA's Medicare "negotiation" provision.[35] This is because drugs selected in the first few years will likely include drugs that have significantly higher utilization and state expenditures per year than drugs selected in later years. For example, Maryland lists Humira as its top drug by spending for 2018-2019 in its annual cost review report, with the next product (Genvoya) listed as nearly half the total spending. By the tenth product listed on the report, the cost is less than one quarter of the top drug (Humira) by spend.[31] Within the next several years, states may see cost savings associated with UPLs on top drug expenditures. However, when UPLs are applied more broadly to unlimited products, their utility is likely to be limited.[36]

2 Patient OOP Cost Reductions

UPLs have also been touted as ways to lower patient out-of-pocket costs and improve patient adherence and access. In their initial efforts around UPLs, state policymakers anticipate, though they do not always mandate, that lowering payment rates for drugs will increase PBM "pass through" of rebates, allowing payers to pass on savings to patients through lower cost sharing or premiums. Historically, this has not happened.[28, 37] Within Colorado's statute, language states that any savings generated to the payer should be passed through to patients through out-of-pocket costs. However, how payers must do this, whether that be deductibles, premiums or lowered drug spending, has not been identified.[28]

Notably, since UPLs have typically only applied to state-regulated commercial health plans (e.g., exchange plans, small group), Medicaid and/or state employee plans, the broader impact on patient out-of-pocket costs may vary depending on whether other markets opt in (e.g., self-funded plans, large group). Though Medicaid may be included in UPL statutes, it is unlikely to have any impact due to low patient cost sharing and mandatory federal rebates for prescription drugs likely being lower than future UPL thresholds. Plans may be unlikely to make large changes to their benefit design structures for smaller markets, such as the exchange markets, leaving benefit design and patient access unchanged.

In addition, setting UPLs without consideration of overall plan economics and current market-based access incentives could inadvertently lead plans to favor non-UPL drugs over UPL drugs. Even if gross costs are lower for a UPL product, plans will base coverage decisions on the value of rebates and net cost to the plan, which could limit patient access to drugs with UPLs.

3

Increased Transparency

Mounting scrutiny on the drug pricing supply chain and increasing patient out-of-pocket costs have increased state efforts to improve transparency.[38] State policymakers are using PDABs to examine relationships between payers, PBMs, manufacturers and other stakeholders as they set UPLs.[39] Most notably, PBMs have been at the center of much of this scrutiny as their role in managing prescription drug benefits and negotiating payment rates is difficult to track. States, including Colorado and Washington, intend to leverage UPL setting information to reduce overall state drug costs and increase transparency and competition among manufacturers and payers.[40]

The PDAB and UPL process typically includes states requiring insurers to report top-spend drugs, either through existing or new reporting pathways, to inform PDAB review. However, much of the efforts to promote transparency through UPLs hinges on the information provided by an APCD. For example, the Colorado APCD is the state's most comprehensive source of health insurance claims information, representing lives across Medicare (Fee-for-Service and Advantage), Health First Colorado (Colorado's Medicaid program) and some commercial health insurance plans.[41] However, the APCD data has limitations, such as the ability to collect complete and accurate information without all ERISA plan contributions. This will impact the ability to use APCDs to support accurate analyses such as affordability reviews.[42]

Unintended Consequences of UPL Setting

UPLs have been enacted by state policymakers with the intention of lowering overall drug spending in the state, improving transparency across the supply chain and enhancing patient affordability. However, as UPLs ignore the interconnected market realities of the drug pricing ecosystem and supply chain, these price-setting thresholds may have unintended consequences across payer and PBM formularies, price-reporting metrics, provider reimbursement and patient plan and benefit options.

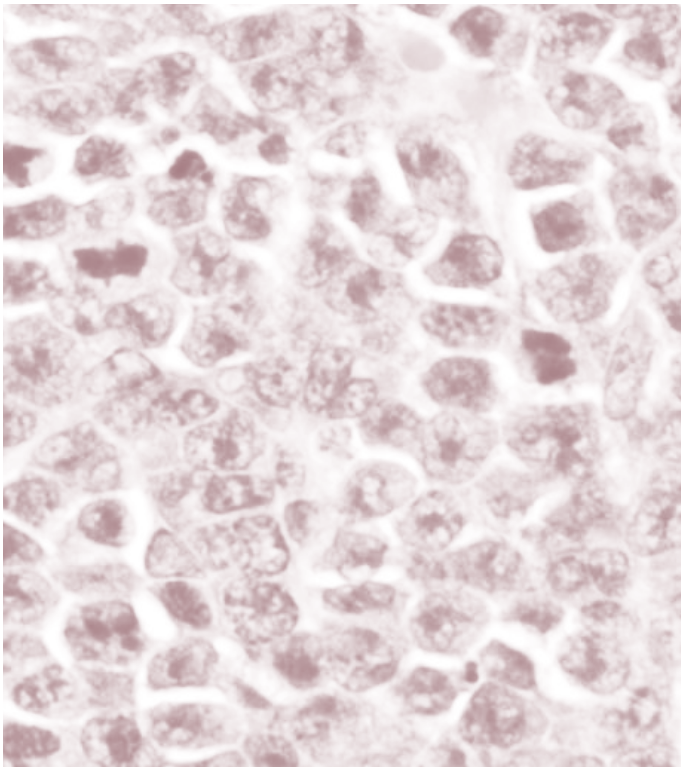
1

Benefit Design and Patient Access

UPL setting for select drugs may shape payer and PBM decision making in ways that could work counter to PDAB's primary intent and increase patient cost sharing or reduce patient access. For example, the process may act cyclically. Manufacturer-provided prescription drug rebates may alter how payers deliver and reform their benefit designs, and lower rebates may result in plans placing medications on higher formulary tiers, which means higher out-of-pocket costs for patients. In addition, this could then affect how patients access medication. The partial list of impacted stakeholders and unintended consequences are as follows:

Pharmacy Benefit Managers (PBMs)

The implementation of price setting in state-regulated commercial markets will have far-reaching effects on payer and PBM practices outside of states with UPLs. In response, PBMs may alter benefit designs to account for their changing rebate structure.[43, 44, 45] This, in turn, may impact patient access to medications and cost sharing, which are closely tied to a drug's placement on plan formularies (e.g., preferred vs. non-preferred).



Pictured: Lymph node.

Patient Cost Sharing

Firstly, UPLs do not necessarily ensure patients see reduced out-of-pocket costs. In addition, benefit design restructuring often results in increased patient cost sharing due to movement across tiers and could reduce patient access. Further, payers and PBMs may shape access by removing UPL products from formularies or reclassifying products to higher, non-preferred tiers. Any benefit design changes that move drugs into non-preferred or brand tiers or result in removal of a drug entirely from a plan's formulary will increase costs to patients (i.e., requires paying for the drug entirely or increases in cost-sharing amounts). Individuals seeking healthcare coverage on the exchanges are increasingly exposed to higher prescription drug cost sharing, as the individual and small group markets have more formulary tiers than large group plans. Nearly 95% of individual market and 93% of small group plans have four or more prescription drug tiers.[46] Additional tiers and PBM movement of drugs to higher tiers will mean higher out-of-pocket costs for patients, as cost sharing is higher for brand and specialty drugs. Additionally, according to HHS, the average deductible on an exchange plan increased from $2,405 to $2,825 in 2021, and the average annual deductible in employer-sponsored insurance has increased by more than 17% over the last five years, more than $2,000.[47, 48] Payer and PBM benefit design changes due to UPLs will have a higher likelihood of adversely impacting patient access, especially in states (e.g., Colorado, Washington) where UPLs will be applied to an unlimited amount of products post-2027.

Average Deductible on an Exchange Plan:

$2,405 2017

$2,825 2021

Average Deductible on Employer-Sponsored Insurance:

↑ 17% in the last 5 years

$2,000+ on average

Copay Assistance

As payers and PBMs implement benefit design changes following UPL application, there is likely to be an increased patient need for manufacturer cost-sharing (e.g., copay) assistance. Copay assistance helps to mitigate the impacts of increased plan and PBM cost-sharing requirements (e.g., deductibles, maximum out-of-pocket costs).[49] For many patients facing high out-of-pocket costs, manufacturer copay assistance programs provide a source of support that improves patient adherence and outcomes. For example, one study found that patients taking HIV or oncology brand medicines using copay assistance saved more than $1,700 in out-of-pocket spending in 2021.[50] As drugs are shifted to higher formulary tiers following UPL setting, increased patient demand for assistance could mean manufacturers reassess and alter eligibility considerations for their copay assistance programs and/or free drug/patient assistance programs (PAPs).

As additional patients seek out manufacturer copay assistance on commercial plans, the implementation of copay assistance diversion (e.g., copay accumulators or copay maximizers, which prohibit or limit manufacturer coupon assistance from counting toward a patient's deductible) could also rise. As such, copay assistance diversion programs could increase patient OOP burden further and prevent them from moving through their benefit.

Patient Choice

Additionally, depending on the volume of UPLs set in a given state, there is potential for market consolidation to limit patient choice. As UPLs grow, both across states and in volume as states become unrestricted in price setting, payers may consider removing themselves from state-regulated markets because of their decreased ability to make a profit based on the spread, decreasing plan choice among patients. Limited plan choice may make plans more sensitive to individuals with high-risk behaviors; as such, they may choose to deny coverage or increase premiums for these individuals.[51]

Plan Participation

While most employer-sponsored insurance is regulated by ERISA and therefore not subject to state PDABs and UPLs, UPL-setting states such as Colorado and Washington have allowed self-funded commercial employers to opt in to UPLs.[52] Self-funded employers could be more likely to opt into UPLs if the state sets a price threshold that is lower than the plan's existing negotiated price or if the plan's volume of UPL drugs is high enough. Higher product volume flowing through UPLs could further limit patient access through benefit design shifts.

Provider Reimbursement

UPL reimbursement pressures could also prompt providers to change referral, prescribing and acquisition patterns for drugs subject to price setting. Smaller practices may be disproportionately impacted by reimbursement cuts and could refer patients to larger sites of care (e.g., outpatient facilities). Where alternatives are available, providers may shift prescribing to other products where reimbursement is more stable.

In one literature review of prescribing habits in oncology, 15 of 18 studies found a correlation between reimbursement and care delivery and responsiveness to financial incentives, suggesting that some oncologists may alter treatment recommendations based on reimbursement considerations.[53]

Lowered reimbursement rates stemming from UPL setting may incentivize providers to prescribe pharmacy benefit drugs instead of medical benefit drugs or non-UPL drugs instead of UPL drugs. The negative financial impact on the traditional provider buy-and-bill system could play into a larger trend that encourages provider consolidation and referrals to larger entities and practices. Finally, UPLs may increase interest in alternatives to buy-and-bill, such as white-bagging, a practice where specialty pharmacies ship a patient's drug directly to the site of care.[54]

Investment in Research and Development

Finally, as manufacturers evaluate the therapeutic areas likely to be subjected to UPLs, they may reassess investment in research and development (R&D) for new therapies or biosimilar competitors to existing drugs. Similar to the potential impacts of the IRA's MFP on selected drugs, manufacturers may be unable to recoup R&D costs if the prices of selected drugs are capped. For example, if "negotiation" were to take place prior to a biosimilar entering the market, the MFP may be set low enough that it deters biosimilar market entry in general. Overall, this could reduce biosimilar launches and negate competition, which may in turn impact manufacturer investment decisions in high-value therapeutic areas that are likely to be subject to price limits such as UPLs.[55, 56]

2

Cascading Changes to Prescription Drug Price Reporting

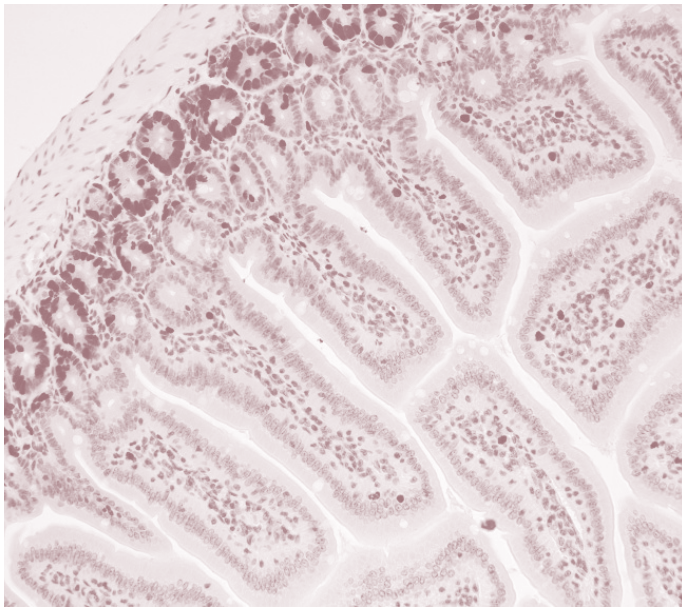
UPL implementation will place downward pressure on a broad range of healthcare stakeholders, including through price reporting metrics such as Medicaid Best Price (BP), Average Manufacturer Price (AMP) and Average Sales Price (ASP). The impact on price reporting metrics may vary, with changes to BP potentially having the largest ripple effect initially. Alternatively, UPL-induced changes to AMP and ASP would occur on a volume-weighted basis, which means that as additional states consider and implement UPLs, ASP and AMP would be affected to a greater degree. **These changes would have consequences that alter pricing outside of the intended markets.**

Medicaid Best Price	Focusing first on BP, base Medicaid Drug Rebate Program (MDRP) liability for brand name drugs is the greater of 23.1% of AMP or the difference between AMP and BP.[57] If a product's UPL were set lower than Medicaid BP, the UPL would set a new BP. If a UPL were to reset BP, markets outside of the UPL state would be affected as a lower BP would alter MDRP calculations and increase the manufacturer's MDRP liability in all states.[58] Additionally, UPL prices would also likely lower AMP on a volume-weighted basis, further altering the MDRP calculation. If BP is too low, it may disincentivize manufacturers from participating in the Medicaid channel.
ASP	Similar effects are expected for ASP for provider-administered drugs. If ASP is lowered due to a UPL, providers reimbursed on an ASP basis (e.g., ASP+6%) would face lower reimbursement, impacting providers outside of UPL states. This consequence is not unique to state UPLs and may be seen with MFP for "negotiated" drugs under the IRA. Once finalized, MFP may be lower than the current ASP, lowering provider reimbursement and creating cascading effects across commercial markets.[59] If provider reimbursement is too low, it may force providers to consolidate practices, contributing to the increasing workforce shortage and/or disincentivizing providers from prescribing or delivering appropriate medication to patients.
340B Pricing	UPL setting will also have cascading effects on the 340B drug pricing program. The 340B program requires manufacturers participating in Medicaid to offer outpatient drugs at a discounted price, no more than a calculated "ceiling price," to eligible entities.[60] Changes to best price and AMP resulting from UPLs will alter the 340B ceiling price (i.e., decreases in AMP could result in 340B entities nationwide purchasing drugs at higher prices). Further, as UPLs reduce insurers' payments for drugs and price reporting metrics, reimbursement for provider-administered drugs could also be negatively impacted, such as by setting a UPL that is lower than the 340B ceiling price, which will alter the margin.

Future of PDABs and UPLs

PDABs are debated and passed into law with the aspiration to be effective tools for states to address perceived rising drug prices and improve patient affordability. **However, much of their efficacy hinges on the ability to produce valuable solutions that work across the drug pricing supply chain and the unproven assumption that cost savings will be passed on to patients.**

To date, state stakeholder efforts to improve drug price transparency and lower costs have been stifled by a lack of long-term consideration and value initiatives. UPLs purportedly offer states a cost-effective short-term option for PDABs and states to lower overall branded drug spending; however, in the long term, their impacts across benefit design, patient access and pricing and contracting may further impede drug pricing reform across state-regulated commercial markets. Moreover, policy changes that focus exclusively on drug pricing at the manufacturer level do not always account for responses from other stakeholders, and hence may not deliver the intended shifts in patient access and affordability. As more states take this approach and select a greater number of drugs each year for UPLs, these issues may be compounded even further.



Pictured: Crypt cells.

In addition to the unintended consequences of UPLs described throughout this paper, future negative effects of price setting may include:

1. Alteration of payer and PBM benefit designs across states and markets (e.g., exchange, self-funded, Medicaid) to provide patients with less generous overall plan choice (e.g., adverse tiering) due to lowered reimbursement for products.
2. Changes in both payer and PBM contracting, as well as manufacturer contracting for products, altering provider reimbursement, 340B contracting and Medicaid rebates.
3. Reductions in manufacturer innovation and research in high-value areas subject to price limits, similar to the effects of the IRA.

In short, states evaluating UPLs may find that UPLs do not help them achieve all of their intended goals and create new negative consequences in the long term, often at the expense of patients and providers. States seeking to implement UPLs should consider the downstream consequences of price setting as UPLs' value may be limited—if not detrimental—in the long term.

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MID-ATLANTIC ASSOCIATION OF
COMMUNITY HEALTH CENTERS

August 26, 2024

Maryland Prescription Drug Affordability Stakeholder Council
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: PDASC Comments

Dear Members of the Maryland Prescription Drug Affordability Board Stakeholder Council,

Thank you for the opportunity to provide comment on the Draft Upper Limit Payment Action Plan. The Mid-Atlantic Association of Community Health Centers, or MACHC, is the federally designated primary care association for Maryland's sixteen community health centers that provide comprehensive primary care to more than 340,000 patients annually. These crucial safety-net providers rely upon the 340B drug pricing program to increase access to affordable medications and primary care services.

MACHC appreciates the board's willingness to consult many stakeholders when evaluating whether upper payment limits will improve medication prices for Marylanders. The association recommends that the board consider an additional factor when assessing the need for upper payment limits. The addition should address the scope and reach of existing affordability programs that apply to the drugs under consideration, including the 340B drug pricing program and patient assistance programs.

Thank you for the opportunity to comment on this process. For additional information, please do not hesitate to contact me at nhoban@machc.com.

Sincerely,

Nora E. Hoban

Nora E. Hoban
Chief Executive Officer
Mid-Atlantic Association of Community Health Centers

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

August 20, 2024

Van T. Mitchell
Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Draft Upper Payment Limit Action Plan

Dear Chair Mitchell,

On behalf of our members operating in Maryland, the National Association of Chain Drug Stores (NACDS) is writing to provide comments on the Maryland Prescription Drug Affordability Board's Plan of Action for Implementing the Process for setting Upper Payment Limits (UPLs). NACDS is committed to providing and promoting high-quality patient care, improving patient access, and lowering healthcare costs across the care continuum for patients while supporting pharmacy providers in the process. To date, Prescription Drug Advisory Board (PDAB) legislation has been enacted in 11 states with the expectation that additional states will soon follow suit.[1] Of the eleven currently enacted PDABs, four contain UPL price limit threshold provisions.[2]

NACDS understands and supports the purpose of the PDABs; however, we fear there may be a significant impact on the availability and accessibility of certain prescription drugs at a patient's neighborhood pharmacy in states where the UPL provision is being considered and effectuated in a manner that fails to ensure fair and adequate reimbursement levels for pharmacies. We believe a failure to do so would have unintended consequences of restricting patient access, exacerbating pharmacy closures, and further decreasing pharmacy reimbursement to unsustainable levels (which are already often below cost) by market-dominant Pharmacy Benefit Managers (PBMs). To that end, our pharmacists and pharmacies are encouraged by the spirit of these policies to help lower prescription drug costs for patients and want to be part of the solution while ensuring appropriate guardrails are put in place to protect the pharmacy providers that deliver frontline healthcare to all Americans.

Pharmacy Reimbursement Overview

Pharmacy reimbursement should be comprised of two parts: 1) the product cost; and 2) a professional dispensing fee across payer markets (e.g., Medicaid, Medicare, commercial) to help ensure reasonable reimbursement and sustainable pharmacy services for beneficiaries. The dispensing fee is typically calculated to incorporate the costs of a pharmacist's time reviewing the patient's medication history/coverage, filling the container, performing a drug utilization review, overhead expenses (rent, heat, etc.), labor expenses, patient

[1] Colorado, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Ohio, Oregon, and Washington.
[2] Colorado, Maryland, Minnesota, and Washington.

counseling, and more to provide quality patient care.[3] For example, under the 2016 Covered Outpatient Drug Final rule, in Medicaid, the Centers for Medicare and Medicaid Services (CMS) requires all states to adopt a more transparent reimbursement model.[4] CMS' final rule utilizes actual acquisition costs and a professional dispensing fee as a benchmark to balance the importance of both the need for affordable solutions and adequate reimbursement for actual costs incurred by pharmacies. In fact, to illustrate further, *Maryland Medicaid* performed a cost of dispensing (COD) study in 2020 that found on average, Maryland pharmacies, including specialty, spent $13.72 to dispense most medications. In the Maryland PDAB plan of action, Board staff are directed to consider the "cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs" when setting a UPL. Additionally, for non-specialty pharmacies only, the average cost of dispensing was $12.03 per prescription.[5]In order to maintain availability and access to certain prescription drugs for Marylanders, it is imperative that these cost considerations include *both* the product costs of the drug and a professional dispensing fee. Said differently, pharmacy reimbursement for prescription drugs subject to the Maryland PDAB's UPL should at a minimum cover pharmacy's cost to acquire and dispense or administer each drug.

Without necessary guardrails to ensure reasonable and sufficient reimbursement for community pharmacies, UPLs could inadvertently result in inadequate or below-cost reimbursement to pharmacy providers and pharmacies by failing to reconcile the difference between the UPL and the pharmacy's acquisition cost and cost to dispense the prescribed drug. This outcome could force pharmacies to either operate at a loss, be unable to stock certain medications that a UPL applies to, or worse, potentially close their doors permanently—negatively impacting Marylanders by ultimately worsening patient outcomes, reducing medication adherence, and increasing prescription abandonment and hospitalizations. Careful consideration of the impact on pharmacies and the communities they serve is both necessary and invaluable to help avoid preventable adverse downstream consequences on patient access to essential medications and overall health outcomes.

Proposed Solutions to Ensure Marylanders' Continued Access to Affordable Medications

NACDS is concerned that UPLs have the potential to further exacerbate inadequate and unreasonable pharmacy reimbursement if they do not incorporate reasonable reimbursement methodologies and practices to help preserve patient access. When an affordability challenge is identified, Maryland PDAB should direct Board staff to ensure that any recommendations concerning the methodologies and criteria factors used to set a UPL must include a pharmacy's actual drug acquisition cost as well as a requirement for applicable payers to provide professional dispensing fees or administration fees aligned with the state's Medicaid's professional dispensing fee rates (discussed above) on any prescription claim subject to a UPL. This will ensure that UPLs do not further strain the already strained finances of pharmacies across Maryland. The Colorado PDAB has already set a precedent of incorporating a pharmacy dispensing fee in its UPL methodology.

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[3]CMS defines the professional dispensing fee at 42 CFR § 447.502 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-447/subpart-I/section-447.502

[4]Medicaid Program; Covered Outpatient Drugs, 81 FR 5169 https://www.federalregister.gov/documents/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs

[5] Maryland Department of Health Survey of the Average Cost of Dispensing a Prescription to Fee-For-Service Maryland Medicaid Participants https://health.maryland.gov/mmcp/pap/docs/MD_2018_COD_Report_final_report%20Jan%202020.pdf

Furthermore, the Maryland PDAB should consider adjusting the UPL in a timely manner, similar to CMS, for selected drugs that fall below the aforementioned acquisition and dispensing costs so that Maryland pharmacies are not subject to underwater reimbursement from PBMs.

NACDS appreciates the Maryland PDAB's sincere efforts to account for the impact of the Inflation Reduction Act's Maximum Fair Price under the new Medicare Negotiation Program and work to reduce prescription drug costs and enhance affordability for patients in the state. We welcome the opportunity to collaborate on the draft working document titled, "*Maryland Prescription Drug Affordability Board Plan of Action for Implementing the Process for Setting Upper Payment Limits*" to address these serious concerns, as all members of the pharmaceutical supply chain will likely be affected, including pharmacies. We strongly encourage the incorporation of adequate reimbursement safeguards for all pharmacies, as mentioned above, in all recommendations concerning the methodologies and factors used to set a UPL. NACDS will continue to urge Maryland lawmakers and the Maryland PDAB to ensure increased patient access and fair and adequate reimbursement for pharmacists, pharmacies of all sizes, and the Marylanders they serve. For questions or further discussion, please contact NACDS at jmccormack@nacds.org (Jill McCormack, Director, State Government Affairs, Pharmacy, Transformation, and Advocacy).

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

3307 Northland Dr, Ste 160 ▪ Austin, TX 78731
www.infusioncenter.org ▪ info@infusioncenter.org

Maryland Prescription Drug Affordability Stakeholder Council
16900 Science Drive
Suite 112-114
Bowie, MD 20715

August 26, 2024

Re: Concerns with Upper Payment Limits (UPLs)

Dear Members of the Prescription Drug Affordability Stakeholder Council,

On behalf of the infusion providers we represent in your state, thank you for your service and commitment to the people of Maryland. As a nonprofit trade association that provides a national voice for non-hospital, community-based infusion providers, we would like to request that you please consider the potential consequences of establishing an upper payment limit for certain infusion drugs that require provider administration.

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of infused and injectable medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in high-quality, non-hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

Our organization writes to express our concerns with the MD PDASC, specifically its ability to establish an Upper Payment Limit (UPL) for drugs that the board believes will cause affordability challenges for Maryland patients and the healthcare system. We applaud Maryland lawmakers for attempting to address drug costs for patients. However, we believe that not only would UPLs for infusion drugs fail to achieve this goal, it would also harm the very vulnerable groups it intends to serve, unless certain measures are taken.

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In practice, we believe the current process to establish UPLs would hinder patient access to life-saving medications by disrupting the delicate economics of medical benefit drug delivery and putting smaller, community providers—that represent the lowest-cost care setting for these expensive medications—out of business. Infusion providers typically acquire, administer, and bill for drugs through a buy-and-bill model. Providers are reimbursed for the drug and provided a small payment for professional services that does not begin to cover the overhead of their business. To remain in business, infusion centers must rely on their drug payments to offset the incredible cost-reimbursement disparity on the professional services side. Drug payments are the economic lynchpin to offset practice expenses, including inventory management, staff salaries, and office space. Unchecked implementation of UPLs would disrupt drug reimbursement for infusion providers and force most of the state's community-based infusion centers to shutter their doors, forcing patients into more expensive hospital care settings or potentially ending their treatments.

In conclusion, an upper payment limit would only limit how much insurers in the state pay for a drug, but it would not change the actual cost of drug acquisition and administration for Maryland providers. Though well-intended, UPLs would harm infusion providers and their patients.

NICA respectfully requests that Maryland lawmakers explore other options or a policy that would exempt infusion providers from the impact of this bill, essentially a provider carve-out. This would avoid disruptions to community-based care delivery and keep Maryland infusion centers in business. Thank you for your consideration. If I can provide any additional information, please do not hesitate to contact me.

Sincerely,

Kindyl Boyer

Kindyl Boyer
Director of Advocacy
National Infusion Center Association
kindyl.boyer@infusioncenter.org

National
Multiple Sclerosis
Society

August 21, 2024

RE: Upper Payment Limit Action Plan and Discussion

Dear Members of the Prescription Drug Affordability Stakeholder Council:

Thank you for the opportunity to submit comments for your August 26 meeting regarding the upper payment limit action plan update. This letter is to provide clarity on the National Multiple Sclerosis Society's (the Society) position related to upper payment limits and the affordability review process.

The Society appreciates the work that both the Maryland Prescription Drug Affordability Boar (Board) and the Prescription Drug Affordability Stakeholder Council (Council) have done in preparing for the possibility of setting upper payment limits (UPLs). The Society views the establishment of UPLs as a possible avenue for lowering out of pocket costs for patients. High out of pocket costs are typically due to co-insurance, which is when the patient must pay a percentage of the wholesale acquisition cost (WAC), or list price, as opposed to a flat copay amount. This is especially true for MS disease-modifying therapies (DMTs) as they are often considered specialty medications. A lower UPL would in turn create lower out-of-pocket costs for those who must pay such a co-insurance.

One important caveat to this is that for infused medications, which include several of the most prescribed MS DMTs, patients face significant additional costs from the administration of, and additional services attached to, an infused product. These additional costs can include infusion center fees, hospital or provider facility fees, additional provider and specialist fees, and ancillary medication charges for side effects or infusion management. A UPL would not affect this additional expense and, as a result, might not substantially lower patient out-of-pocket costs for the overall infused medication services. For these reasons, we appreciate the intent of this body to look beyond just list price and consider the cost to administer and deliver the medications as well.

The Society understands the complex nature of the healthcare system and, in particular, drug cost and pricing. Solving affordability issues will not be simple which is why we thank this group for taking into consideration so many different aspects of the structure in place including information from insurers, pharmacy benefit managers (PBMs), and wholesale distributors. We encourage the Board and Council to continue to collect as much data as possible, provided it comes from evidence-based sources.

The Society knows that the price of the medication is but one aspect of what makes access to these high-cost prescriptions out of reach for many people with MS and other conditions. The Society will continue to look at the entire healthcare system and encourages legislatures and entities like the Maryland Prescription Drug Affordability Board to do likewise.

National
Multiple Sclerosis
Society

Finally, while we appreciate the opportunity to comment throughout this process, we would encourage the Board and Council to do more outreach to people directly impacted by the high cost of prescription drugs to ensure that their voices are heard regarding access and affordability issues throughout the system.

We thank you for this opportunity and would be happy to answer any questions you may have. Please do not hesitate to reach out to Laura Hoch at laura.hoch@nmss.org should you wish to discuss any of these points in greater detail.

Respectfully,

Laura Hoch
AVP, State Advocacy & Policy
National Multiple Sclerosis Society

Value of Care Coalition

August 21, 2024

Prescription Drug Affordability Stakeholder Council
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: August 26th Council Meeting – UPL ACTION PLAN AND IMPLEMENTATION PROCESS

Dear Members of the Stakeholder Council:

As a broad coalition of advocacy organizations representing patients, caregivers and health care providers, we write to share our concern with the draft UPL Action Plan being reviewed by the Council during the August 26 meeting and currently under consideration by the Prescription Drug Affordability Board.

We recognize the importance of lowering health care costs and do appreciate some aspects of the draft plan. The coalition will be submitting full comments on the draft plan prior to the submission deadline on August 26. However, we hope that the Stakeholder Council will consider the following comments as it discusses the draft plan during its meeting:

- The draft plan states that "The Board shall set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences." However, it does not identify outcomes or consequences that are of concern and that should be minimized. Nor does the plan define the threshold for tolerance of these outcomes and consequences in order to be determined minimal.

- The plan acknowledges that an upper payment limit may not be the best policy solution to help contain costs yet provides no additional options. The lack of interest from the Board in additional policy options that can save cost while protecting patient access validates advocates' concerns about the narrow view being taken by the Board regarding health care costs.

- Several options for arriving at a UPL price are suggested in the draft plan. Many options raise patient concerns, such as utilizing QALY-like metrics that are widely viewed as discriminatory, referring to pricing in countries with healthcare systems unlike ours, and referring to federal pricing with a still-unknown impact on access. None of the options allow for consideration of individual patient needs.

- The plan references opportunities for stakeholders to provide input throughout the process but does not formalize that process. Concerns remain that opportunities provided are inadequate, including 90-second time limits for oral comment, and actual consideration by the board for any comments received.

- No information is included in the plan that ensures patient savings through the implementation of the upper payment limit.

Given the gravity of the decisions being made by the Board, the Value of Care Coalition has concerns with the haste expressed during its last meeting. This push has led to shifting meeting dates and overlapping comment periods, causing confusion for interested stakeholders. Other states' PDABs have acknowledged their own process-related shortcomings, now focusing on the necessity to be thorough and considerate when making decisions that impact patient health.

As the Stakeholder Council discusses the draft UPL Action Plan and offers its feedback to the Board, we ask that you consider these concerns.

Thank you,

Derek Flowers
Executive Director
Value of Care Coalition