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

Image Info: Microscopic Biology.

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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.
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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]

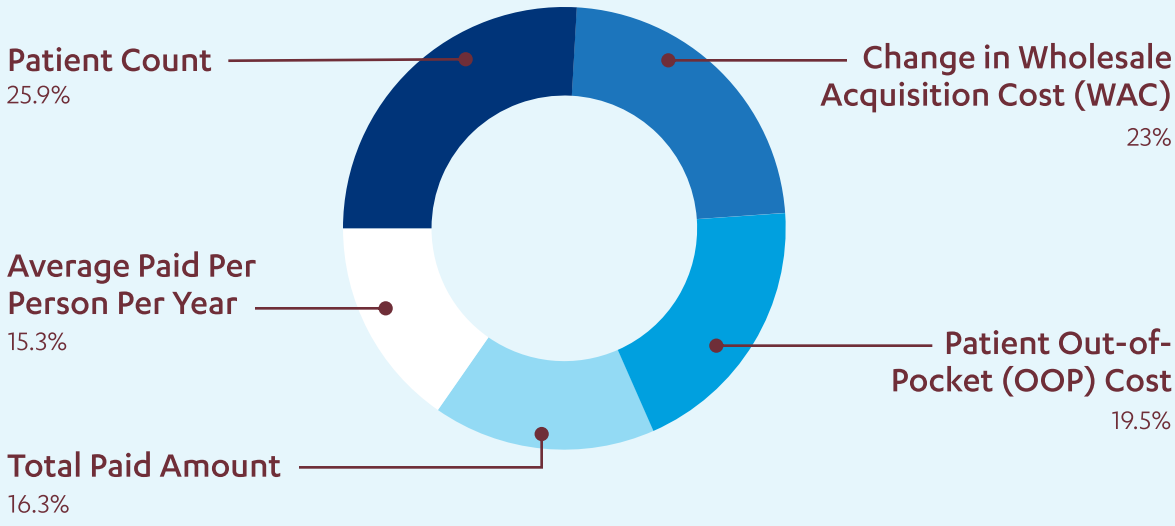
The 5 drugs selected for affordability review were:

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:



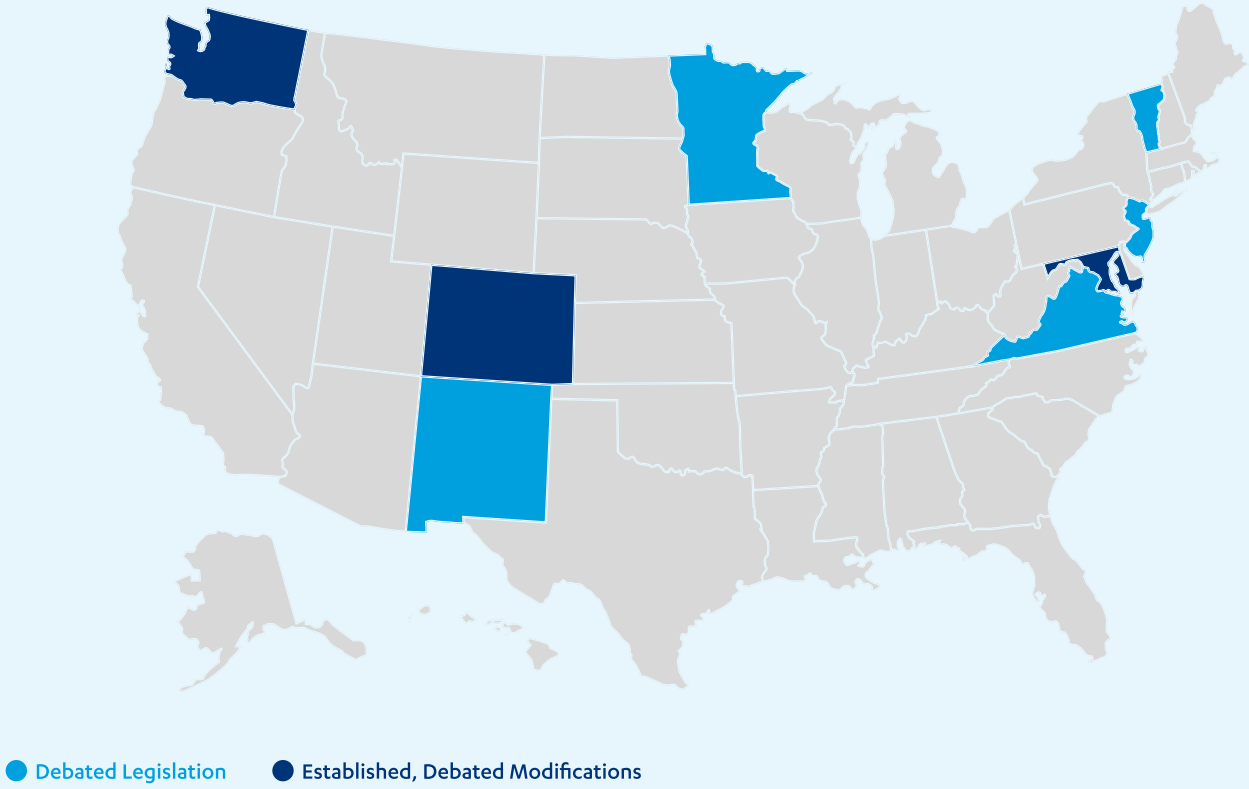
Key Characteristics of PDABs Across Three Enacted State Laws

	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.

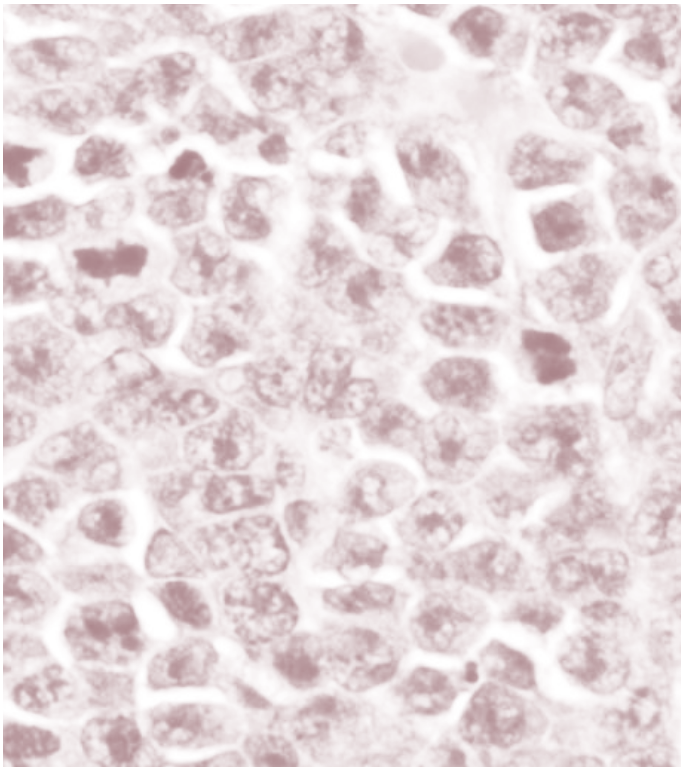
1

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

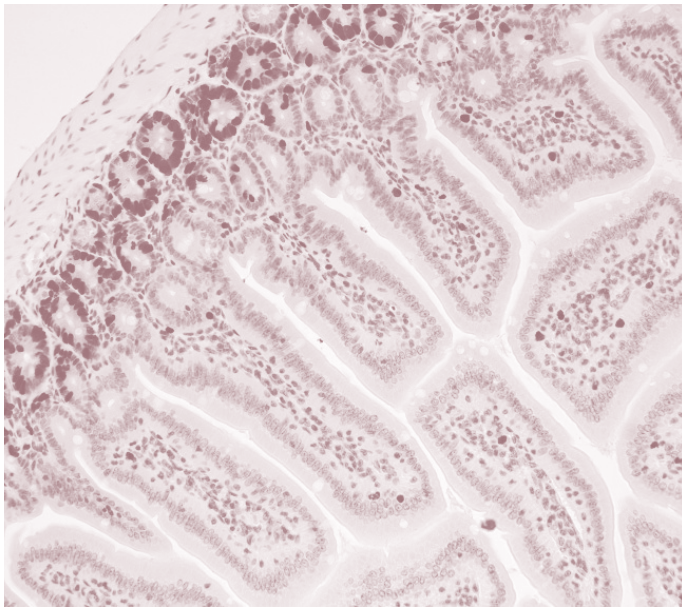
UPL implementation will place downward pressure on a broad range of healthcare stakeholders, including through price reporting metrics such as Medicaid Best Price (BP), Average Manufacturer Price (AMP) and Average Sales Price (ASP). The impact on price reporting metrics may vary, with changes to BP potentially 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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