Prescription Drug Affordability Boards and the Impact on Cancer Care

Background

Addressing the costs of cancer care is crucial to accomplishing the mission of the American Cancer Society Cancer Action Network (ACS CAN) to end cancer as we know it for everyone. ACS CAN has long fought for public policies that support the availability and affordability of medically necessary prescription drugs.

In recent years, as means of reducing spending, federal and state governments have increasingly focused on enacting prescription drug pricing legislation:

- *Medicare Negotiation:* At the federal level, the Inflation Reduction Act (IRA) allows Medicare to negotiate the price of prescription drugs directly. These negotiated prices, termed as the Maximum Fair Price (MFP), will go into effect in 2026, with an increasing number of drugs – including cancer drugs - negotiated each year. [1]

- *Prescription Drug Affordability Boards:* At the state level, an increasing number of legislatures are enacting Prescription Drug Affordability Boards (PDABs) to recommend policy solutions to lower or limit spending on prescription drugs.

For cancer patients, affordability and access are equally critical to ensuring they receive the best treatment to survive their disease. While intended to increase affordability, PDAB policies may negatively impact cancer patients' access to critical medications if not designed and implemented with careful consideration of the unique needs and treatment complexities inherent in oncology care.

Overview of Prescription Drug Affordability Boards

PDABs were first established in 2017, and as of December 2023, 11 states have enacted PDABs or similar entities[2-15], and several states have proposed legislation under consideration[16-30].

Characteristics of Prescription Drug Affordability Boards

Though function varies by state, enabling legislation establishes who will serve on the PDAB, how it will identify drugs with affordability challenges, and what the output or next steps will be.

- *Composition:* PDABs typically consist of around five members with expertise in health policy, healthcare economics, or clinical medicine.

- *Identification of "Unaffordable" Drugs:* In most states, PDABs use criteria to identify specific drugs that are considered high cost. These criteria are typically included in statute and/or established through implementing regulations and include drug pricing metrics (e.g., launch price, annual price increases). Most PDABs focus on brand-name medications, although generic and biosimilar therapies may be included if their list price is above a given threshold.

- *Authority:* While some PDABs issue broad policy recommendations that apply across therapeutic areas, others focus on limiting spending on identified drugs. Some state PDABS have the authority to establish **upper payment limits (UPLs)** or propose Medicaid supplemental rebates or public payer spending targets.

Upper Payment Limits (UPLs)

Since 2019, several states have established PDABs with the ability to set UPLs for prescription drugs deemed unaffordable to consumers in the state.[2-15] Notably, PDABs with UPL authority are likely to have the greatest impact on cancer patients. While the intention of UPLs is to improve patient affordability, there are concerns that implementation could actually limit access more broadly. For example, this could occur if insurers preference products that are subject to a UPL or if the policy discourages development of future cancer therapies. The impact of UPLs could be positive, negative, or a mix of both, depending on how they are implemented.

At this point, the process for setting UPLs is unclear, as no states have progressed to this stage. In some states, statute requires PDABs to consider certain factors, such as the cost of administering, dispensing, and distributing the drug, shortage status, and reference prices. Throughout all these processes, there is a lack of a clear, standardized methodology in how these factors are weighted to select drugs for review and ultimately set a UPL.

- *Mechanics*: UPLs do not govern what a manufacturer can charge for a prescription drug. Instead, UPLs determine: ○ The maximum amount purchasers (e.g., wholesalers, pharmacies, providers) can pay, or ○ The maximum amount payers (e.g., insurers, pharmacy benefit managers (PBMs)) can reimburse, for a prescription drug dispensed or administered to individuals in the state (either in person, by mail, or through other means). While states are technically not regulating manufacturers, the rationale behind UPLs is that they will lower their prices to continue selling products in the state.

- *Applicability:* States cannot force self-insured plans regulated at the federal level by the Employee Retirement Income Security Act (ERISA) to limit reimbursement to the UPL, but PDAB legislation typically includes an opt-in provision for these plans.

- *Drug Selection:* Before setting UPLs, PDABs must first identify eligible drugs, select drugs for affordability review, and then conduct these reviews to determine if a drug is unaffordable to consumers. PDABs with UPL authority use drug-pricing metrics, established through statute, implementing regulations, or both, to identify eligible drugs. The criteria PDABs use to select drugs for affordability review vary but may include:
  - Drug pricing information
  - Approval pathway
  - Cost to insurers
  - Patient out-of-pocket costs
  - Manufacturer rebates
  - Availability of therapeutic alternatives

- *Affordability Reviews:* PDABs may use similar criteria to conduct affordability reviews, in addition to factors meant to represent consumer access to the product, impact on total cost of care, and stakeholder input.

Summary: UPL Process

Implications for Cancer Patients

There are several challenges for cancer patients and survivors that may arise from the authorization of PDABs. These include:

Patient Access Limitations and Affordability Concerns

Varying processes

While there is overlap, each PDAB uses different criteria when identifying eligible drugs, selecting drugs for affordability review, and conducting reviews to determine if a UPL should be set. The factors most important to cancer patients, such as access to innovative treatments, out-of-pocket costs and utilization management, are not valued uniformly across PDABs. Both enacted and proposed PDABs typically do not consider net price or patient access when identifying eligible drugs. Instead, products are determined eligible solely based on their list price, before considering discounts manufacturers may provide to insurers and other stakeholders. While PDABs may consider average patient cost sharing as part of the selection or affordability review process, they are not required to determine if high out-of-pocket costs are due to plan benefit design or the price of the drug. Additionally, few PDABs are required to consider if utilization management practices (e.g., prior authorization, step therapy) are limiting access to needed medications, rather than solely the price of a product. If PDABs fail to adequately consider the factors that most impact patients, they risk setting UPLs for drugs that are already affordable instead of targeting their efforts elsewhere.

Savings for patients

Typically, PDAB legislation requires state-regulated commercial plans to use any savings from UPLs to benefit consumers. However, plans are not required to pass these savings on in the form of lowered outof-pocket costs for the patients using drugs subject to UPLs. Instead, the plans may use the savings to, for example, lower premiums for all beneficiaries while maintaining patient cost sharing for drugs subject to

UPLs at the same level. Patients should share directly in any savings derived from reimbursing pharmacies or providers at the reduced UPL rate.

Development of future cancer therapies

With an increasing number of states establishing PDABs, in future years UPLs could be implemented for drugs across the country. This broad adoption, particularly in states with large patient populations, could disincentivize innovation of future cancer therapies. In most states, drugs are eligible for affordability review regardless of how long they have been on the market or if there is a generic or biosimilar available. If UPLs are implemented shortly after drugs are launched, manufacturers may increase launch prices to make up for lost revenue. In addition, generic and biosimilar manufacturers may be reluctant to enter the market if a brand-name product is already subject to UPLs in multiple states.

These effects could be magnified if states tie UPLs to MFPs under the IRA. Manufacturers subject to reduced prices in Medicare and multiple states will face further pressure to reduce investment in research and development or increase launch prices of future products. If multiple states require the MFP to automatically apply to all drug purchases in the state (regardless of consideration for a UPL) this could create a cascading effect as products are quickly subject to reduced prices in multiple markets.

Cancer Stakeholder Involvement

Limited transparency

While PDABs are relatively new entities, there are already transparency concerns regarding the way they operate. While statute may require PDABs to consider certain factors when analyzing drugs, they are free to weigh these factors as they see fit with little to no explanation. Additionally, the methodology for setting UPLs is often omitted from enacting legislation and left entirely up to the PDAB, which may or may not publish the details of how a UPL was determined. This lack of transparency makes it difficult for oncology stakeholders to provide meaningful feedback. Even if PDABs release data detailing the criteria considered, this information may be difficult to understand without knowledge of pharmaceutical pricing and market dynamics, limiting the ability of patients to participate in a process that will eventually impact the care they receive.

Lack of oncology expertise

Legislation establishing PDABs frequently specifies the expertise that individuals must possess to serve on the board or an advisory council to the board. Typically, PDAB members must possess an advanced degree and expertise in health policy, healthcare economics, or clinical medicine. Legislation may be more prescriptive in the expertise or experience of members of the advisory council. Example criteria include requiring members who are or who represent healthcare consumers, patient advocacy organizations, patients with chronic diseases, labor unions, employers, insurers, PBMs, providers, manufacturers, researchers, wholesalers, and pharmacists. While these are important perspectives, almost no PDABs or advisory councils are required to have a member who is an oncologist. Given that cancer is one of the most common chronic diseases in the U.S. and therapies frequently exceed the pricing metrics used to determine eligibility for affordability reviews, PDABs will likely focus their efforts on cancer medications in the future. Given the unique pricing and reimbursement dynamics for cancer therapies, having an oncologist provide input on PDAB processes would help ensure providers and cancer patients are not unintentionally harmed.

Guardrails to Ensure Choice & Access

Potential for steering

Most enacted and proposed legislation establishing PDABs with UPL authority requires state-regulated commercial insurers to limit reimbursement to the UPL (this provision is optional for federally regulated plans subject to ERISA). However, no legislation governs how insurers cover drugs subject to UPLs. Given that these products may become the lowest-cost option, insurers may be incentivized to steer patients toward drugs with UPLs. Cancer patients who rely on other medications in the same class may suddenly have to step through a drug subject to a UPL, complete more burdensome prior authorization, or face higher cost sharing if non-UPL products are moved to a higher formulary tier. Patients who have already found a given drug to be effective should not be forced to disrupt or delay their care.

Lack of uniform exceptions

Currently, only one enacted PDAB is prohibited from setting UPLs for drugs designated by the FDA as treating a rare disease or condition[6], and there is proposed legislation[22] to remove this protection. Patients with cancer may already face challenges finding effective therapies and there are concerns that UPLs may hinder access when there are limited treatment options available. While rare therapies naturally treat smaller patient populations, they still require significant investment to develop. As a result, manufacturers may be particularly sensitive to price control programs when determining whether to develop future therapies. Additionally, while most states require PDABs to consider FDA shortage status before and after a UPL is set, few prohibit PDABs from selecting these drugs in the first place or require the UPL to be lifted if a drug does enter a shortage. Cancer patients facing access concerns due to shortages should not have to contend with additional barriers that could worsen the situation. Prohibiting UPLs for rare therapies and those in shortage would help ensure continued patient access to existing and future medications.

Comparative effectiveness considerations

When conducting affordability reviews or value assessments, nearly all PDABs consider the availability and cost of therapeutic alternatives to a selected drug. However, it is unclear if and how PDABs will determine therapeutic alternatives if a drug has multiple indications, which is common for oncology products. Even if a selected drug and therapeutic alternative's indications match, the effectiveness of these therapies may differ by patient. Generalizations about which product is more effective could harm patients with a different clinical response. Additionally, most PDABs have not described how they will consider off-label use, even if recognized in clinical compendia. All uses of a drug, and its appropriate therapeutic alternatives, should be reflected when conducting comparative effectiveness research.

While already included in most legislation, PDABs should be prohibited from using quality-adjusted life years (QALYs) in their analyses of a drug's effectiveness, which aim to evaluate the effectiveness of medical interventions by considering the quantity and quality of life gained, with one QALY representing one year of so-called 'perfect health'. However, this measure fails to consider how individual cancer patients value the benefits and quality of life provided by different treatments.

Access variability

Cancer patients' access to medications could be negatively impacted if a UPL is set too low or if Medicaid managed care organizations are allowed to implement access restrictions (if manufacturers do not agree to a state-recommended price). In states where the UPL is set so low that it may have a detrimental spillover impact, manufacturers could choose to stop selling the product in the state (by refusing to sell

the drug at the UPL). In this instance, patients requiring the drug in question would be forced to travel further for their treatment, burdening the patient and their caregivers. For example, selling a drug at a low UPL in one state may reset the "best price" at which manufacturers must offer the drug to all state Medicaid programs; this dynamic may incentivize manufacturers to elect not to offer the UPL rate. This is more likely to occur if the drug in question has a large proportion of Medicaid patients. In contrast, manufacturers of products subject to UPLs with large Medicare or commercial patient populations are unlikely to take this approach.

Even if a manufacturer did not leave a given state, it could still reduce access in other ways to compensate for the lost revenue. This could include limiting or eliminating patient assistance programs, which would impact patients in all regions. While currently only applicable in New York, states should not punish Medicaid beneficiaries by allowing contracted managed care organizations to reduce access to a drug through formulary restrictions if the manufacturer does not provide a supplemental rebate deemed appropriate by state agencies.[8] Increased access restrictions without clinical justification could delay cancer patients' access to needed therapies.

Oncologist reimbursement

Oncologists are responsible for more than the cost of cancer medications, they are also financially responsible for acquiring, storing, and administering drugs. If PDABs do not consider these additional costs and set the UPL below the actual costs of providers, oncology practices will be reimbursed at a rate lower than their total costs. Without adequate reimbursement, oncologists could be forced to stop providing certain drugs. PDABs must consider total costs when determining the UPL to ensure practices are reimbursed at a rate that allows them to continue to provide all appropriate cancer medications and maintain a profit.

While some current PDABs include administration and delivery costs as required factors to consider when determining the MFP, this dynamic provides further justification for requiring an oncologist to serve on the PDAB or its advisory council. Additionally, provisions governing what providers can bill non-state regulated plans that are not required to reimburse at the UPL, such as ERISA and Medicare Part D plans, should be avoided until states can confirm that practices are being reimbursed adequately by state regulated plans.

Uncertainties Regarding Prescription Drug Affordability Boards

As discussed previously, the ultimate impact of PDABs, and UPLs, on cancer patients will depend on how states implement these policies and how stakeholders react. Depending on the factors considered when setting a UPL, and whether savings are passed on to plan beneficiaries, cancer patients could experience greater affordability. However, if plans use utilization management to prefer products subject to a UPL over competitors, access could be reduced for cancer patients across the board. The level of impact will also depend on whether non-state regulated plans (subject to ERISA) opt into UPL reimbursement. If they do not, many patients will not be affected by PDAB proceedings. Additionally, manufacturers response to PDABs will likely depend on how UPLs are set. If UPLs are set significantly below current prices and/or are set for many drugs (or concentrated in one therapeutic area), development of future therapies is more likely to be adversely impacted. If PDABs conduct affordability reviews but determine not to set UPLs for most drugs, or limit how low a UPL may be established, manufacturers may make little to no changes. Finally, manufacturers are unlikely to completely stop providing a product in a state where it is subject to a UPL unless there are severe financial consequences for doing so.

State of the States

Enacted Prescription Drug Affordability Board Legislation

Summary: Enacted PDABs

State	Authority	Applies To	Exceptions	MFP References
Maryland	Establish UPLs (no limit) UPL action plan must be approved by Legislative Policy Committee or the Governor and Attorney General	Public purchasers and payers	Drugs on FDA shortage list	MFP must be considered during selection for affordability review
Colorado	Establish 12-18 UPLs per year	All purchasers and payers in state	None	MFP must be considered when setting UPL
Washington	Establish 12 UPLs per year, beginning in 2027	All purchasers and payers in state	Drugs on the market for less than 7 years Drugs designated by FDA as solely treating a rare disease or condition	None
Minnesota	Establish UPLs (no limit)	All purchasers and payers in state	None	Requires UPL to be set at MFP
New York	Recommend Medicaid supplemental rebates State may impose formulary restrictions if manufacturer does not come to rebate agreement with Medicaid program	Medicaid	None	None
Massachusetts	Recommend Medicaid supplemental rebates	Medicaid	None	None
Maine	Set public plan spending targets	Public plans	None	PDAB recommended the legislature establish UPLs for high-cost drugs by referencing Canadian drug prices and/or MFPs
New Hampshire	Set public plan spending targets	Public plans	None	None
Oregon	Conduct affordability reviews for 9 drugs annually and at least one insulin product Issue reports and recommendations only	NA	Drugs designated by FDA as solely treating a rare disease or condition	PDAB recommended the legislature apply MFPs to all prescription drugs dispensed or administered to individuals in state

Ohio	Issue reports and recommendations only	NA	None	None
New Jersey	Issue reports and recommendations only	NA	None	None

States with Upper Payment Limits: Maryland, Colorado, Washington, and Minnesota

There are currently four states with PDABs that have UPL authority, all of which are relatively early in the affordability review and UPL setting process.

Maryland

Maryland (MD) became the first state to enact a PDAB with UPL authority in 2019.[4] However, because some of the PDAB's powers were scheduled to expire in December 2022, legislation was passed in April 2023 re-establishing the PDAB's original duties.[5] Unlike other states, the MD PDAB is required to draft an action plan for setting UPLs that must be approved by the Legislative Policy Committee or the Governor and Attorney General before UPLs can be implemented. As of December 2023, the PDAB is considering different frameworks that could be used to set UPLs, including value assessments, budget assessments, and reference pricing.[31] There is no limit on the number of UPLs the PDAB may set, and UPLs will only apply to public purchasers and payers.[4,5] Notably, when selecting drugs for affordability review the PDAB must consider if a drug is subject to an MFP under the IRA (per implementing regulations) and is prohibited from selecting drugs on the FDA shortage list.[4,5,32]

Colorado

The Colorado (CO) PDAB was established in 2021 (and expanded in 2023) but is the furthest along in the process of setting UPLs. The CO PDAB may set 12-18 UPLs per year, which will apply to all purchasers and payers in the state. [2,3] Per implementing regulations, when determining the UPL for selected drugs, the CO PDAB must consider the MFP, if applicable.[33] Throughout the summer of 2023, the PDAB published and updated an eligible drug dashboard listing selection criteria for each drug and ranking drugs according to factors prioritized by the board.[34] In August 2023, the PDAB selected five drugs for affordability review.[35] The PDAB is currently in the process of conducting affordability reviews on the selected drugs, which includes gathering feedback from stakeholders (e.g., patients, caregivers, and individuals with scientific and medical expertise). While timelines could shift, the PDAB may begin adopting UPLs for the selected drugs it deems unaffordable in early to mid-2024.[36]

Stakeholders, including manufacturers, providers, and patients, have been heavily involved in the CO PDAB process. After the eligible drug dashboard was published, there were numerous complaints from manufacturers and patient groups that the dashboard did not contain correct or relevant information. In stakeholder feedback sessions, patients and caregivers have repeatedly stated that the drugs in question are affordable due to low-cost sharing and/or manufacturer patient assistance programs, although insurance design (e.g., prior authorization) was mentioned as a barrier to access. Patients, particularly those using a selected drug indicated solely for a rare disease, have expressed concerns that a UPL would decrease or eliminate access to the product in CO.[37]

Washington

Enacted in 2022, Washington's (WA) PDAB is permitted to set UPLs for up to 12 drugs per year, which will apply to all purchasers and payers in the state. However, UPLs may not go into effect until January 1, 2027. Statute also prohibits the PDAB from establishing UPLs for drugs that have been on the market for

less than 7 years and/or are designated by the FDA to treat a rare disease or condition, including rare cancers. If the PDAB decides not to set a UPL for a selected drug, the WA Healthcare Authority may impose a penalty on manufacturers for increased revenue resulting from price increases.[6]

Minnesota

In May 2023, Minnesota (MN) became the latest state to establish a PDAB with UPL authority. While the state is still in the process of making appointments to the board, eventually the PDAB will be able to set UPLs on an unlimited number of drugs per year. MN is the only state that requires the UPL to set at the MFP if applicable, rather than only including the MFP as a factor that must be considered. Notably, the advisory council to the PDAB (which provides recommendations to the PDAB but does not vote) is required to have a member who is a community oncologist.[9]

States with Medicaid supplemental rebates: New York and Massachusetts

New York (NY) and Massachusetts (MA) established PDAB-like authorities in their state Medicaid programs in 2017 and 2019, respectively. In both states, if a drug meets certain cost-related criteria, and a supplemental rebate (discount) agreement cannot be reached between the manufacturer and the Medicaid program, the manufacturer is referred to another government agency (the Drug Utilization Review Board (DURB) in NY and the Health Policy Commission (HPC) in MA). This agency will conduct a value assessment of the drug, based on clinical effectiveness, cost-related metrics, and potentially manufacturer-submitted information, to determine what it deems an appropriate supplemental rebate.[8,9]

In NY, manufacturers may not be referred to the DURB unless the state is expected to exceed its prescription drug spending cap for the Medicaid program (also established through legislation in 2017). If the manufacturer and NY Medicaid program cannot reach an agreement after the DURB issues a recommended supplemental rebate, and the Medicaid program is still expected to exceed the prescription drug spending cap, the drug may be subject to access restrictions such as removal from formularies, reduced reimbursement, and favoring of therapeutic alternatives (with exceptions in certain instances).[8] While agreements are confidential, the NY Medicaid program has used this process to negotiate supplemental rebates from several manufacturers, primarily for drugs targeting rare diseases.[38] In MA, the enacting legislation does not include provisions allowing access restrictions if an agreement is not reached.[9]

States with public payer spending targets: Maine and New Hampshire

In 2019 and 2020, respectively, Maine (ME) and New Hampshire (NH) passed legislation establishing PDABs with the authority to determine prescription drug annual spending targets for public payers and recommend policies to meet those targets. The PDABs may also set spending targets, and issue recommendations, for specific drugs they expect will create affordability challenges for the state.[10,11] PDABs in both states have issued annual reports since enactment. The NH PDAB's most recent recommendations include increasing the use of biosimilars, creating a purchasing cooperative for PBMs, and reducing drug waste.[39] Notably, the ME PDAB has repeatedly recommended the state establish UPLs for high-cost drugs by referencing Canadian drug prices and/or MFPs set through the IRA.[40, 41]

States with report/recommendations only: Oregon, Ohio, New Jersey

Several states have created PDABs, or PDAB-like entities, with similar functions to those outlined above, but without the authority to set UPLs or recommend supplemental rebates or public plan spending

targets. Instead, these entities assess the affordability of prescription drugs and issue recommendations to the legislature or state agencies.

Oregon

Created in 2021, the Oregon (OR) PDAB has the authority to conduct annual affordability reviews on 9 prescription drugs and at least one insulin product and issue recommendations.[12] Like states with UPL authority, the OR PDAB is governed by criteria in statute and implementing regulations that determine which drugs may be selected for review. However, the PDAB is prohibited from selected drugs designated by the FDA as treating a rare disease or condition, including rare cancers.[12] In 2022, the OR PDAB released a report overviewing analyzed drugs as well as recommendations, including a recommendation to apply MFPs to all prescription drugs dispensed or administered to individuals in the state.[42] In November 2023, the PDAB published a list of 16 drugs and several insulin products that it will narrow to 9 before it begins the next round of affordability reviews.[43]

In July 2023, OR passed a bill requiring the PDAB to create a plan for setting UPLs, which is due to the legislature on September 14, 2024.[13] If the OR legislature expands the PDAB's authority to allow it to set UPLs, its prior experience in conducting affordability reviews could expedite the process, especially compared to states establishing new PDABs.

Ohio and New Jersey

Enacted in 2019 and 2023, respectively, the Ohio (OH) and New Jersey (NJ) entities are referred to as Prescription Drug Transparency and/or Affordability Councils. These organizations may collect data from manufacturers, wholesalers, payers, and PBMs, but are not required to conduct affordability reviews of individual drugs. Instead, they issue recommendations on how prescription drug spending and consumer costs can be addressed, although this may include recommendations targeting specific high-cost drugs.[14,15]

Proposed Prescription Drug Affordability Board Legislation

Summary: Proposed PDABs

State	Summary	Applies To	Exceptions	MFP References
Legislation to Establish a PDAB with UPL Authority				
Connecticut	Establish 8 UPLs per year Recommended UPLs must be submitted to the Office of Health Strategy and the General Assembly	All purchasers and payers in state	None	Requires MFP to apply to all prescription drugs dispensed or administered to individuals in state
Rhode Island	Establish UPLs (no limit)	All purchasers and payers in state	None	None
Vermont	Establish UPLs (no limit)	All purchasers and payers in state	None	Requires UPL to be set at MFP
Wisconsin	Establish UPLs (no limit)	All purchasers and payers in state	None	None

Virginia	Establish 12 UPLs annually between 2024-2027	All purchasers and payers in state	None	Requires UPL to be set at MFP or lower
Michigan	Establish UPLs (no limit) Must select drugs for affordability reviews within 18 months of enactment	All purchasers and payers in state	None	None
New Jersey	Require PDAB to conduct a study on UPLs and drug importation and submit recommendations to legislature Establish maximum allowable prices (no limit)	Public purchasers and payers	None	None
	Legislation to Expand UPL Authority of Existing PDAB			
Washington	Remove limitations on current PDAB, including: • Allow UPLs in 2026 (currently 2027) • Allow UPLs to be set for drugs designated by FDA as being solely for the treatment of a rare disease or condition in 2027 (currently prohibited outright) • Change eligibility criteria to allow lower cost medications to be reviewed • Remove requirement for a drug to be on the market for 7 years before selection Allows insurers to reimburse over UPL in certain instances	All purchasers and payers in state	None	None
Oregon	Establish UPLs (no limit)	All purchasers and payers in state	None (exceptions in current law)	None
	Legislation to Establish a PDAB without UPL Authority			
Connecticut	Identify prescription drug affordability challenges and submit recommendations to the legislature	NA	None	None
New Mexico	Identify prescription drug affordability challenges and submit recommendations to the legislature	NA	None	None

An increasing number of states have proposed legislation to establish PDABs in recent years. In 2023, five states passed legislation to either alter an existing PDAB (MD, CO, OR)[3,5,13] or create a new one (MN, NJ)[7,15]. As of December 2023, ten other states have proposed but not yet enacted bills, most of which aim to either establish a PDAB with UPL authority or expand this authority within existing PDABs.[16-30] No states have proposed legislation to create PDABs focused on Medicaid supplemental rebates or public plan spending targets. While only one existing PDAB is required to set the UPL at the MFP when applicable[7], three states have proposed legislation with similar or more expansive provisions[16,20,21].

States with Legislation to Create a PDAB with UPL Authority: Connecticut, Rhode Island, Vermont, Virginia, Michigan, New Jersey, and Wisconsin

Seven states have proposed legislation to establish a PDAB with the authority to set UPLs. In six of these states, Connecticut (CT), Rhode Island (RI), Vermont (VT), Virginia, (VA), Michigan (MI), and Wisconsin (WI), the PDAB would have the authority to set UPLs that apply to all purchasers and payers in the state.[16,19,20,21,23-25,28] Only the bills in VA and CT would limit the number of UPLs the PDAB may set annually.[16,21] Notably, legislation in VT and VA would require the PDAB to set the UPL at (VT)[20] or below

(VA)[21] the MFP. While CT's bill would require recommended UPLs be submitted to the Office of Health Strategy and the General Assembly, rather than going into effect immediately, the legislation also includes more expansive authorities than current PDABs. This includes a requirement to use reference pricing (consider drug prices in other states and/or countries) when setting the UPL. Additionally, MFPs would be applied to all drug purchases in the state, regardless of whether the product was under consideration for a UPL.[16]

While NJ already has a Drug Affordability Council, there are two proposed bills to create a distinct PDAB, both of which would apply to public purchasers and payers only.[17,18] The first would require the PDAB to conduct a study on UPLs and drug importation and submit an action plan to the legislature on whether to proceed with one of these policies.[18] The other would allow the PDAB to set an unlimited number of maximum allowable prices that govern how much a manufacturer could charge for prescription drugs sold for use in NJ.[17] This provision would function differently than UPLs, which regulate purchasers and payers in the state.

States with Legislation to Expand the UPL Authority of an Existing PDAB: Washington, Oregon, and Minnesota

WA and OR proposed legislation to expand the authority of existing PDABs, despite both being established in the last two years.[22,27] The bill in WA would remove several of the limitations currently in place, including allowing the PDAB to set UPLs in 2026 (currently 2027) and target drugs designated by FDA as being solely for the treatment of a rare disease or condition in 2027 (currently prohibited outright). The bill would also change eligibility criteria to allow lower-cost medications to be reviewed and remove the requirement for a drug to be on the market for 7 years before selection. Notably, the bill also includes exceptions that allow insurers to reimburse above the UPL in certain instances.[22] While OR passed legislation requiring the PDAB to develop an action plan for establishing UPLs in July 2023, there is also a proposal to allow the PDAB to immediately begin setting UPLs for drugs subject to affordability reviews.[27]

While MN has not proposed legislation to alter the newly created PDAB, there was a competing proposal that included more expansive eligibility criteria, allowing more drugs to be reviewed. The bill also included a provision requiring providers who dispense or administer drugs in the state to bill all payers at the UPL, regardless of whether an ERISA-regulated plan or Medicare Part D plan reimburses at a higher amount.[26]

States with Legislation to Create a PDAB Without UPL Authority (Connecticut and New Mexico)

Policymakers in New Mexico (NM) and CT proposed legislation to create PDABs with more limited authority. These PDABs would identify prescription drug affordability challenges and submit recommendations to the legislature.[29,30]

References

1 Inflation Reduction Act of 2022, H.R.5376, 117th Congress. (2022) https://www.congress.gov/bill/117th-congress/house-bill/5376

2 SB21-175, Colorado 2021 Regular Session. (2021) https://leg.colorado.gov/bills/sb21-175

3 HB23-1225, Colorado 2023 Regular Session. (2023) https://leg.colorado.gov/bills/hb23-1225

[4] HB0768, Maryland 2019 Regular Session. (2019)
https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/hb0768/?ys=2019rs

[5] HB0279, Maryland 2023 Regular Session. (2023)
https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/hb0279?ys=2023RS

[6] SB5532, Washington 2022 Regular Session. (2022)
https://app.leg.wa.gov/billsummary?BillNumber=5532&Year=2021

[7] SF2744, Minnesota 2023-2024 Regular Session. (2023)
https://www.revisor.mn.gov/bills/bill.php?b=Senate&f=SF2744&ssn=0&y=2023

[8] S2007B, New York 2017-2018 Legislative Session. (2017)
https://www.nysenate.gov/legislation/bills/2017/S2007

[9] H.4000, Massachusetts 2019-2020 Legislative Session. (2019)
https://malegislature.gov/Bills/191/H4000

[10] LD1499, Maine 2019 Regular Session. (2019)
https://legislature.maine.gov/LawMakerWeb/summary.asp?ID=280073010

[11] HB1280, New Hampshire 2020 Regular Session. (2020)
https://www.gencourt.state.nh.us/bill_status/legacy/bs2016/bill_docket.aspx?lsr=2032&sy=2020&sortoption=billnumber&txtsessionyear=2020&txtbillnumber=hb1280

[12] SB844, Oregon 2021 Regular Session. (2021)
https://olis.oregonlegislature.gov/liz/2021R1/Measures/Overview/SB844

[13] SB192, Oregon 2023 Regular Session. (2023)
https://olis.oregonlegislature.gov/liz/2023R1/Measures/Overview/SB192

[14] HB166, Ohio 2019-2020 Regular Session. (2019)
https://www.legislature.ohio.gov/legislation/133/hb166

[15] S1615, New Jersey 2022-2023 Session. (2023) https://www.njleg.state.nj.us/bill-search/2022/S1615

[16] Substitute for S.B. No. 10, Connecticut Session Year 2023. (2023)
https://www.cga.ct.gov/asp/CGABillStatus/cgabillstatus.asp?selBillType=Bill&bill_num=SB10

[17] A3245, New Jersey 2022-2023 Session. (2023) https://www.njleg.state.nj.us/bill-search/2022/A3245

[18] A1747, New Jersey 2022-2023 Session. (2023) https://www.njleg.state.nj.us/bill-search/2022/A1747

[19] HB5507, Rhode Island 2023 Regular Session. (2023)
http://webserver.rilegislature.gov/BillText/BillText23/HouseText23/H5507.pdf

[20] S.98, Vermont 2023-2024 Session. (2023) https://legislature.vermont.gov/bill/status/2024/S.98

[21] HB1596, Virginia 2023 Session. (2023) https://lis.virginia.gov/cgi-bin/legp604.exe?231+sum+HB1596

[22] HB1269, Washington 2023 Regular Session (2023) https://app.leg.wa.gov/billsummary?BillNumber=1269&Initiative=false&Year=2023

[23] SB0482, Michigan 2023 Regular Session. (2023) https://www.legislature.mi.gov/(S(0ic2zyukiq35eyzhzkyvcu53))/mileg.aspx?page=GetObject&objectname=2023-SB-0483

[24] SB0484, Michigan 2023 Regular Session. (2023) https://www.legislature.mi.gov/(S(1fgnhxo3lu4lvxlzmlt3uj23))/mileg.aspx?page=GetObject&objectname=2023-SB-0484

[25] SB0845, Michigan 2023 Regular Session. (2023) https://www.legislature.mi.gov/(S(2hwn0nj4su10larqy2ihnbmf))/mileg.aspx?page=GetObject&objectname=2023-SB-0485

[26] HF17, Minnesota 2023-2024 Regular Session. (2023) https://www.revisor.mn.gov/bills/bill.php?b=House&f=HF0017&ssn=0&y=2023

[27] SB404A, Oregon 2023 Regular Session. (2023) https://olis.oregonlegislature.gov/liz/2023R1/Measures/Overview/SB404

[28] SB718, Wisconsin 2023-2024 Session. (2023) https://docs.legis.wisconsin.gov/2023/proposals/reg/sen/bill/sb718

[29] Substitute for Raised H.B. No. 6830, Connecticut Session Year 2023. (2023) https://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=HB06830&which_year=2023

[30] HB51, New Mexico 2023 Regular Session. (2023) https://www.nmlegis.gov/Legislation/Legislation?chamber=H&legtype=B&legno=51&year=23

[31] Maryland Prescription Drug Affordability Board. (n.d). PDAB 2023 Board Meeting. https://pdab.maryland.gov/2023_board_meeting.html

[32] Maryland Prescription Drug Affordability Board. (2023, July 17). COMAR 12.01.01.01-05 – Cost Review Study Process. https://pdab.maryland.gov/documents/regulations/Cost_rev_study_process_COMAR1401040105_redline.pdf

[33] Colorado Prescription Drug Affordability Board. (2023, January 20). 05 Upper Payment Limit Methodology Policy. https://drive.google.com/drive/folders/1SVcgHEv4CNgyspCnm79VnqFkJjG2PaDH

[34] Colorado Division of Insurance. (2023, October 19). Colorado PDAB 2023 Eligible Drug Dashboard. https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDas hboard/0_Navigation?publish=yes

[35] Colorado Prescription Drug Affordability Board. (2023, August 4). 8.4.23 PDAB Meeting. https://drive.google.com/drive/folders/1QEPsCdEjquYrG4JTzsbooikoyQknbnHt

[36] Colorado Prescription Drug Affordability Board. (2023, December 15). 12.15.23 PDAB Meeting. https://drive.google.com/drive/folders/1qNHshVjA-UgqGb6xxT0TWqOt1oIDpiLT

[37] Colorado Prescription Drug Affordability Board. (n.d.). Written Testimony. https://drive.google.com/drive/folders/1G8NAb5Cc6dmeyxD1y5tQvjRfSemtCGqH

[38] Silverman, Ed. (2020, July 27). New York panel seeks extra Medicaid rebates from Biogen for pricey rare disease drug. STAT. https://www.statnews.com/pharmalot/2020/07/27/new-york-medicaidbiogen-rebates-spinraza/

[39] New Hampshire Prescription Drug Affordability Board. (2023, November 1). Prescription Drug Affordability Board 2023 Annual Report. https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents2/2023pdabanrepfinal.pdf

[40] Maine Prescription Drug Affordability Board. (2023, January 24). 2022 Report of the Maine Prescription Drug Affordability Board: Recommendations to Reduce Prescription Drug Spending. https://www.maine.gov/bhr/oeh/sites/maine.gov.bhr.oeh/files/inline-files/2022%20Prescription%20Drug%20Affordability%20Board%20Annual%20Report.pdf

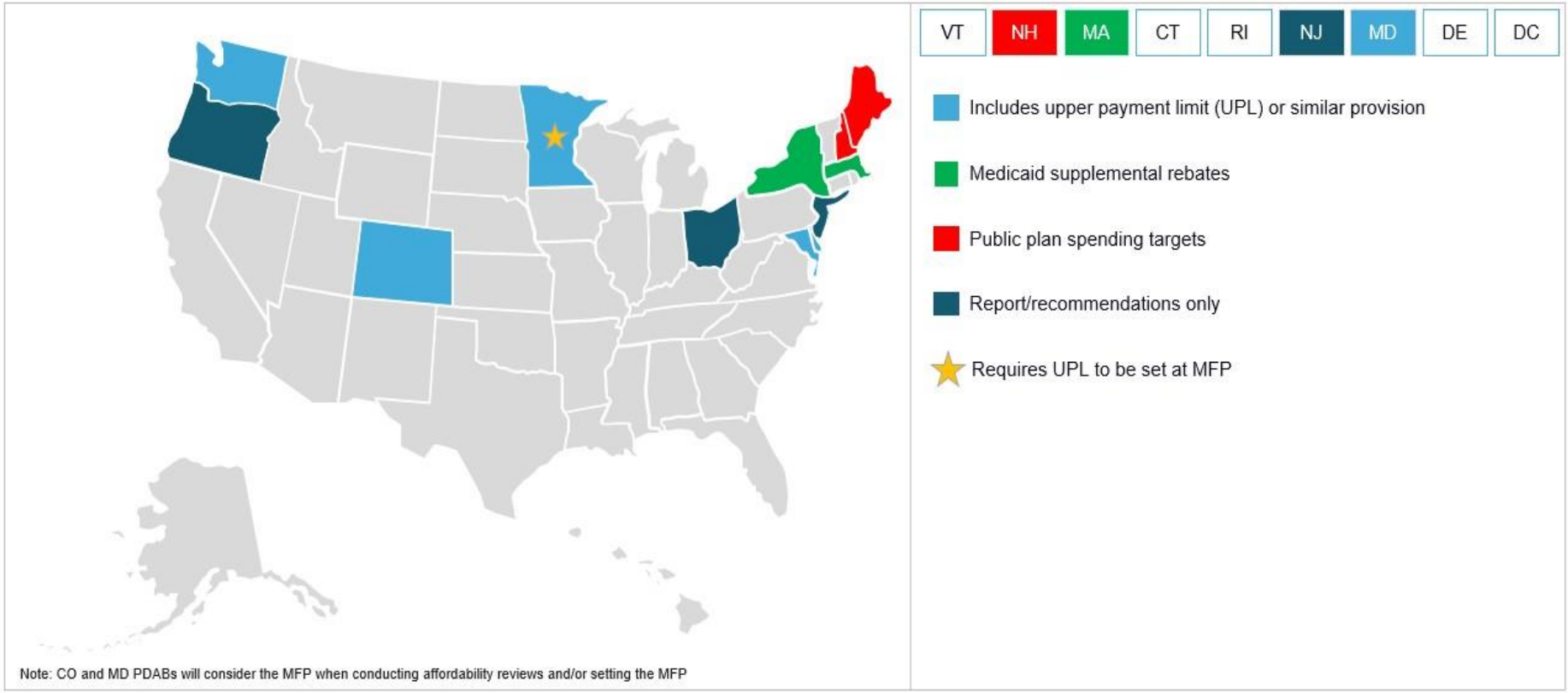
[41] Maine Prescription Drug Affordability Board. (2022, March 2). Report of the Maine Prescription Drug Affordability Board: Recommendations to Reduce Prescription Drug Spending. https://www.maine.gov/bhr/oeh/sites/maine.gov.bhr.oeh/files/inline-files/2021%20Prescription%20Drug%20Affordability%20Board%20Annual%20Report.pdf

[42] Oregon Prescription Drug Affordability Board. (2022, December 19). 2022 Report for the Oregon Legislature. https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Report_2022.pdf

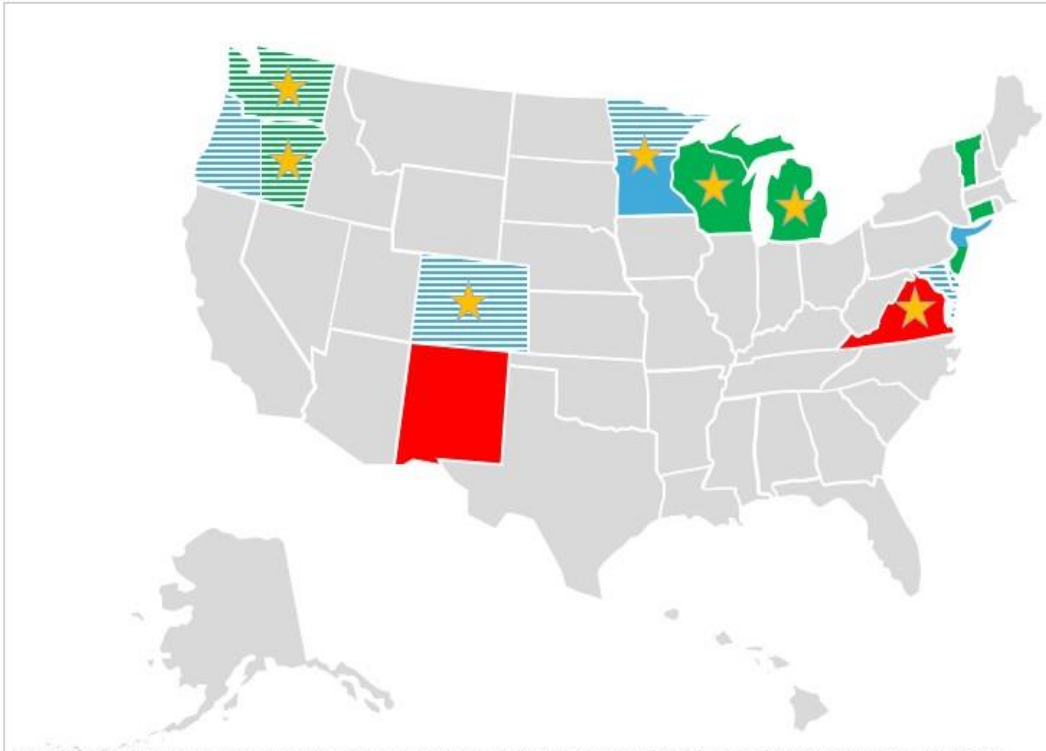
[43] Oregon Prescription Drug Affordability Board. (2023, November 15). Oregon PDAB drug and insulin subset list. https://dfr.oregon.gov/pdab/Documents/OR-PDAB-drug-%20insulin-subset-lists.pdf

Appendix

Enacted Prescription Drug Affordability Boards



2023 Proposed and Enacted PDAB Legislation



Note: If multiple bills have been proposed in a state, and only some include UPLs, the state is listed as having legislation that includes a UPL provision

VT NH MA CT RI NJ MD DE DC

Passed

Proposed

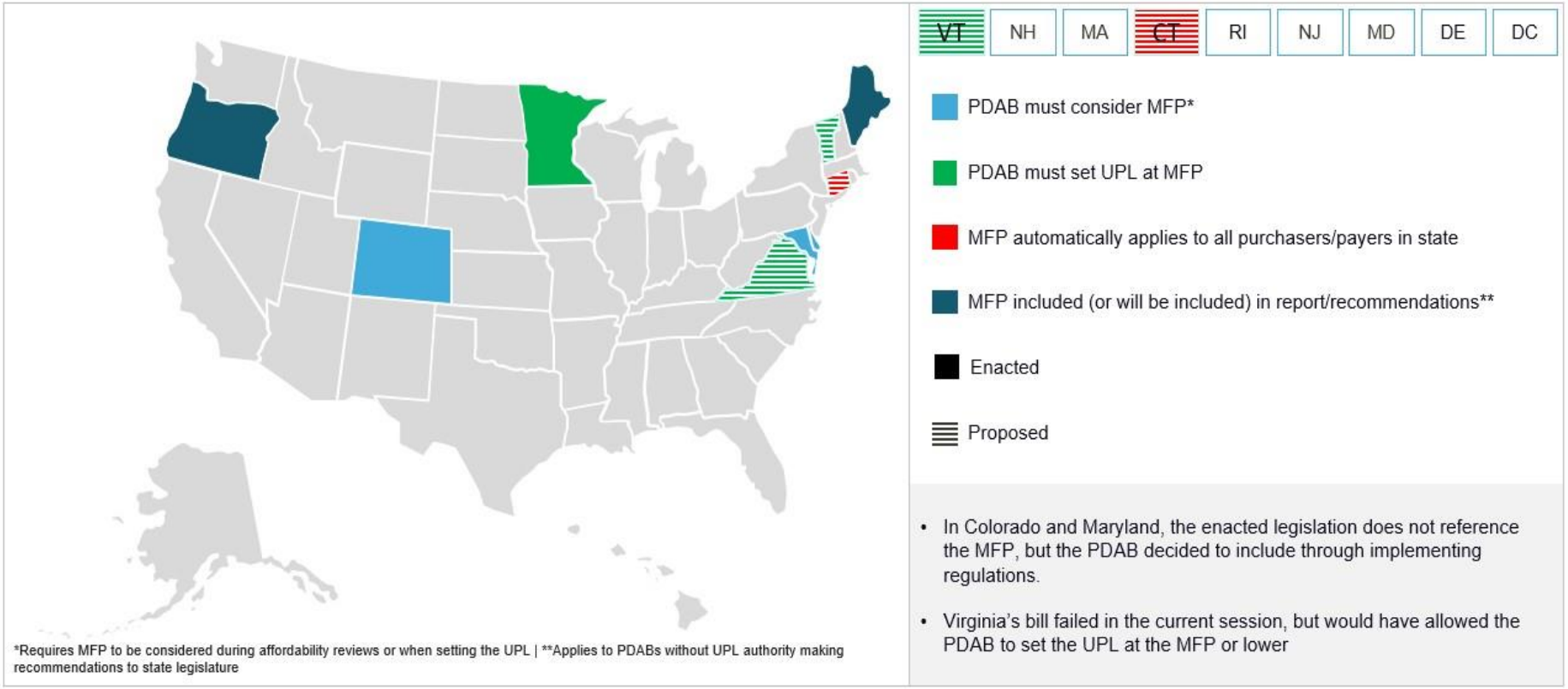
Failed

Updates current PDAB

Includes upper payment limit (UPL) or similar provision

- Bills in VT, MN, and VA include references to maximum fair prices (MFPs) established through the Medicare negotiation program when determining the UPL.
- CT includes a provision prohibiting all purchasers in the state from purchasing a drug for a cost greater than its MFP, regardless of inclusion on the list of drugs subject to an UPL.

Proposed and Enacted PDAB Legislation: MFP References



PDAB Implementation Timeline