Learnings from State and Federal Drug Pricing Negotiations Across the United States: The Impact of Prescription Drug Affordability Boards

HPR135

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Objective

To understand the landscape of state-level Prescription Drug Affordability Boards (PDABs), categorize their structures and goals, and analyze the first set of results shared by states, comparing them to results of price negotiation arising from the Inflation Reduction Act (IRA).

Background

- Following passage of the IRA in 2022, the US Centers for Medicare and Medicaid Services (CMS) conducted a series of drug pricing negotiations from 2023–2024 seeking to establish a maximum fair price (MFP) that Medicare would be able to pay for up to 10 prescription drugs. The number of negotiations would increase in following years.[1]
- Simultaneously, several states have established PDABs, with varying levels of authority, to review state-level drug pricing and spend.
- Prior research from 2024 identified states that had implemented legislation authorizing the creation of PDABs and compared drug selection criteria.[2,3] However, at the time of publication no state had completed pricing review. This research aims to build upon past work and evaluate the published rationales for drug price negotiation.

Methods

- Targeted searches were conducted in January 2025 to identify state PDABs that had newly been authorized since December 2023. A PDAB was considered to be any state-appointed entity tasked with evaluating and regulating prescription drug prices to ensure they remain affordable for consumers, regardless of target population (i.e. state-level public payers, commercial health plans, individuals).
- State PDAB websites were reviewed for details on the status of negotiations. If any decisions were made on drugs to select for further scrutiny (e.g. secondary review, price negotiation), published justifications underwent comprehensive review and extraction.
- Data on affordability review processes, outcomes, and justifications were extracted into a prespecified extraction grid.

Results

PDABs

- As of April 2025, 11 states have established a PDAB or similar entity (**Figure 1**), up from eight states in April 2024. These PDABs fall into two categories:
  - **"Affordability Review" Boards**, tasked with identifying and reviewing medicines creating affordability challenges, and when appropriate, setting legally binding upper payment limits (UPLs) for payers.
  - **"Strategic" Boards**, tasked with recommending spending targets for public purchasers and/or strategies to optimize affordability.
- Of these boards, one state PDAB (Ohio) had its authority lapse and is no longer permitted to make recommendations. Four states (Colorado, Maryland, Minnesota, and Washington) have allowed state PDABs to set UPLs.
- Three states (Colorado, Oregon, and Maryland) have published the most information related to drug price negotiations.
  - The Colorado PDAB has progressed the furthest, having selected five drugs for in-depth review (**Table 1**). While a large amount of background information was reviewed, key pieces of information were specifically flagged as being discussed during the final affordability decision meeting. Every decision made by the Colorado PDAB was unanimous. The first rulemaking hearing to vote on UPLs will take place in May 2025.
  - The Maryland PDAB recently received authority to formally set UPLs, having selected drugs for further review. The Oregon PDAB has identified drugs for further analysis, with the preliminary list to be narrowed in future reviews (**Figure 2**).

CMS Negotiations

- Ten drugs were chosen for CMS Medicare Part D negotiations, to take effect in 2026, while an additional 15 were selected for 2027 and are currently undergoing negotiations.
- Eleven drugs were selected for further review by both CMS and at least one state PDAB, and three other drugs were selected for further review by at least two state PDABs.

Conclusion

The number of states with drug price evaluation or negotiation mechanisms continues to increase, with increasing numbers of drugs selected by CMS as well.

Despite different areas of focus and different criteria for drug selection, several drugs have already been selected for negotiation or further scrutiny by multiple bodies. Manufacturers should consider the implications of having multiple sets of negotiations with different evidence requirements and goals.

FIGURE 1

PDABs established in the US

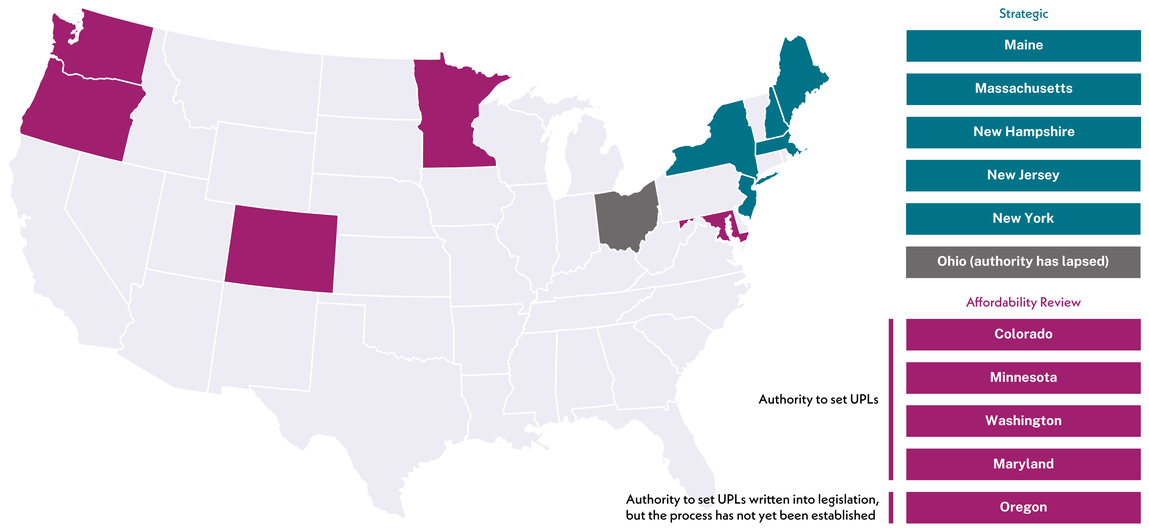

FIGURE 2

Comparison between drugs chosen for state and federal negotiations

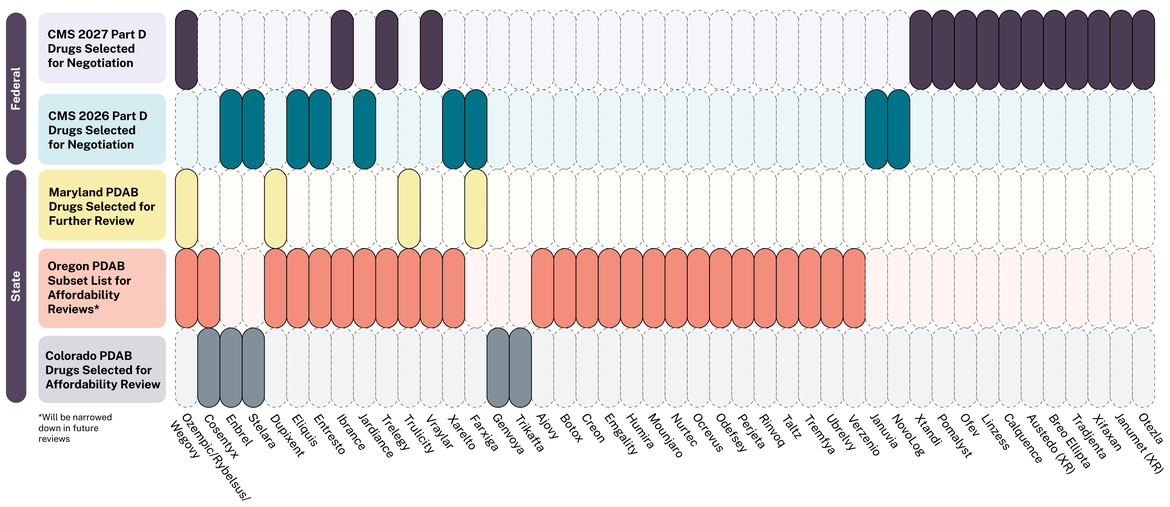

TABLE 1

Key discussion points for Colorado PDAB decision making

	Cosentyx (secukinumab)[4]	Enbrel (etanercept)[5]	Genvoya (elvitegravir/ cobicistat/ emtricitabine/ tenofovir alafenamide)[6]	Stelara (ustekinumab)[7]	Trikafta (elexacaftor/ tezacaftor/ ivacaftor)[8]
Final affordability decision	Unaffordable	Unaffordable	Not unaffordable	Unaffordable	Not unaffordable
OOP cost concerns?	Yes; OOP costs were "significant"	Yes; higher than some therapeutic alternatives, and concerns that Colorado patients may be paying higher OOP costs than those outside of Colorado	No; average individual OOP costs have not risen significantly in the past few years	Yes; average OOP costs are very high and are increasing substantially year over year	Yes; recent doubling of total patient OOP amounts since 2021–2022
WAC price concerns?	Yes; WAC increasing faster than alternatives and inflation	Yes; high changes in WAC were considered	Not discussed	Yes; increasing WAC and gross-to-net sales suggest rebates are high and not passed on to consumers	Yes; noted the drug is "extraordinarily expensive"
Insurance premium concerns?	Yes; one of the top drugs to cause an increase in premiums	Not discussed	Not discussed	Yes; concern for higher premiums due to increasing costs	Yes; concern from some carriers that Trikafta is one of the top drugs causing premiums to rise
Patient support programs reviewed?	Yes; manufacturer program was considered not to be sustainable and reliable for the long-term	Not discussed	Yes; considered broad availability from patient support programs and stage + federal support	Yes; programs are not guaranteed and may be a burden to consumers	Yes; patient support programs were considered to be fragile, though stakeholders provided input noting their benefits to date
Drug utilization?	Not discussed	Yes; utilization of therapeutic alternatives was considered	Yes; utilization expected to decrease as newer drugs are introduced	Yes; most utilized compared to therapeutic alternatives and increasing for commercially insured patients	Yes; increasing utilization since approval
Safety and efficacy discussion?	Yes	Yes	Not discussed	Yes	Yes

Abbreviations: CMS: Centers for Medicare and Medicaid Services; **IRA:** Inflation Reduction Act; **MFP:** maximum fair price; **OOP:** out-of-pocket; **PDAB:** prescription drug affordability board; **UPL:** upper payment limit; **US:** United States; **WAC:** wholesale acquisition cost; **XR:** extended release.

References: [1]KFF (2025). FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program. Available at: https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/ [Last accessed 15 April 2025]; [2]Eustace J. et al. PT2. Presented at ISPOR International, 5–8 May 2024. Atlanta, GA, USA; [3]NASHP (2025). State Laws Passed to Lower Prescription Drug Costs: 2017–2025. Available at: https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2025/ [Last accessed 15 April 2025]; [4]Colorado PDAB (2024). Affordability Review Summary Report: Cosentyx; [5]Colorado PDAB (2024). 2023 Affordability Review Summary Report: Enbrel; [6]Colorado PDAB (2024). 2023 Affordability Review Summary Report: Genvoya; [7]Colorado PDAB (2024). Affordability Review Summary Report: Stelara; [8]Colorado PDAB (2023). 2023 Affordability Review Summary Report: Trikafta. **Acknowledgements:** The authors thank Jenny Chen, Costello Medical, for graphic design assistance.