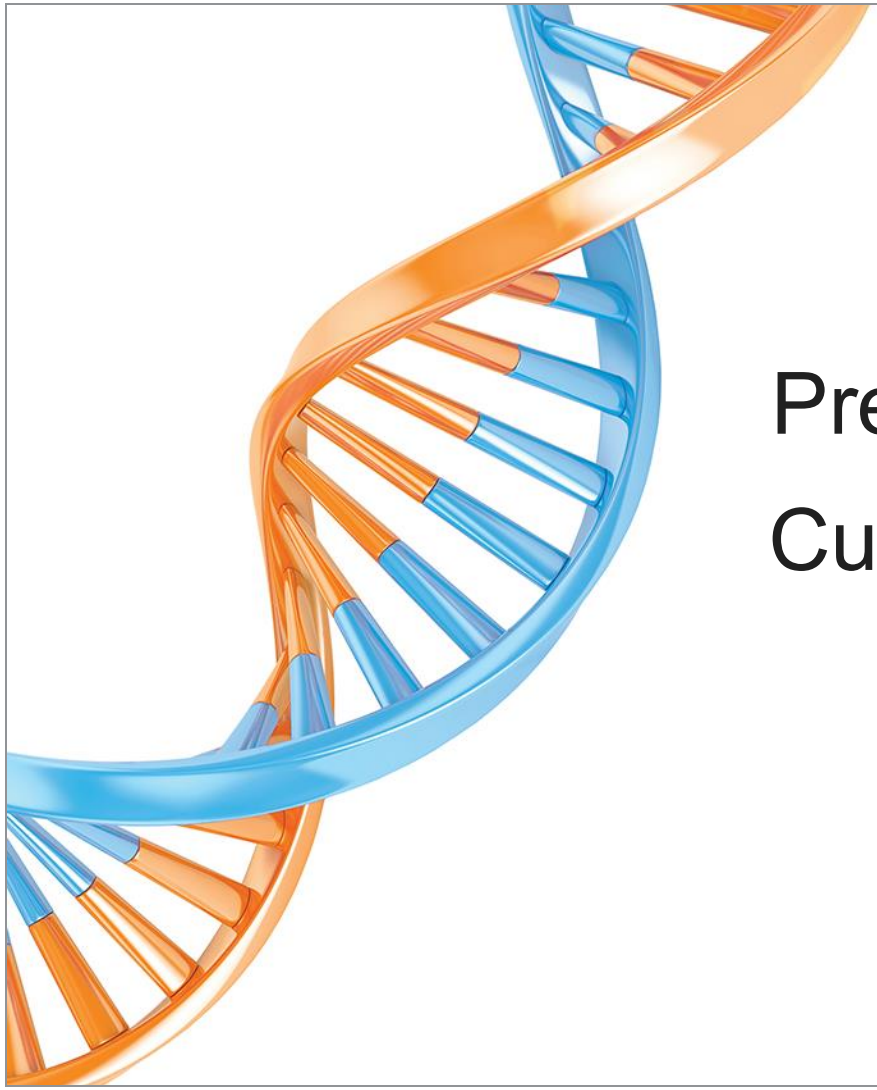

Prescription Drug Affordability Boards: Current Landscape and Future Trends

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CRA Charles River Associates

Speaker

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- Ph.D. in Political Science, Syracuse University – Maxwell School
- Specializes in U.S. healthcare policy and litigation.

Policy Team at CRA: Published analyses on implications of the Inflation Reduction Act's Medicare Drug Price Negotiation Program on patients and access to innovation.

Litigation Team at CRA: Assisted on expert reports and economic analyses in antitrust, anti-steering, price fixing, commercial disputes, and intellectual property litigation in the United States, Canada, and international arbitrations.

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The Pharmaceutical Industry: Background

The pharmaceutical industry is unique in a number of ways:

Innovative products that are costly to develop.

- **High Cost:** Cost to develop a drug is between **$300 million to $4.5 billion**.
- **High Risk:** Risk of a drug candidate failing during development is **90%.**

Pricing decisions are not made by consumers.

- **Numerous actors** (insurers, PBMs, governmental actors) help **determine drug pricing**.
- **Patient choices not the primary driver** of the list prices of pharmaceutical products.

Significant impact on **patient quality of life**.

- Innovation in the pharmaceutical industry can **significantly improve the quantity and quality of patient's lives.**
- **Value** in the pharmaceutical industry is multi-faceted: **benefiting patients, health care sustainability, and the economy**

The Pharmaceutical Industry: Emerging Challenges

Paying for innovative products.

Increasing **costs of covering innovative products for insurers.**

Increasing **out-of-pocket costs for patients**.

Pricing decisions are increasingly being made by **governmental actors**.

Federal level: Inflation Reduction Act's Medicare Drug Price Negotiation Program

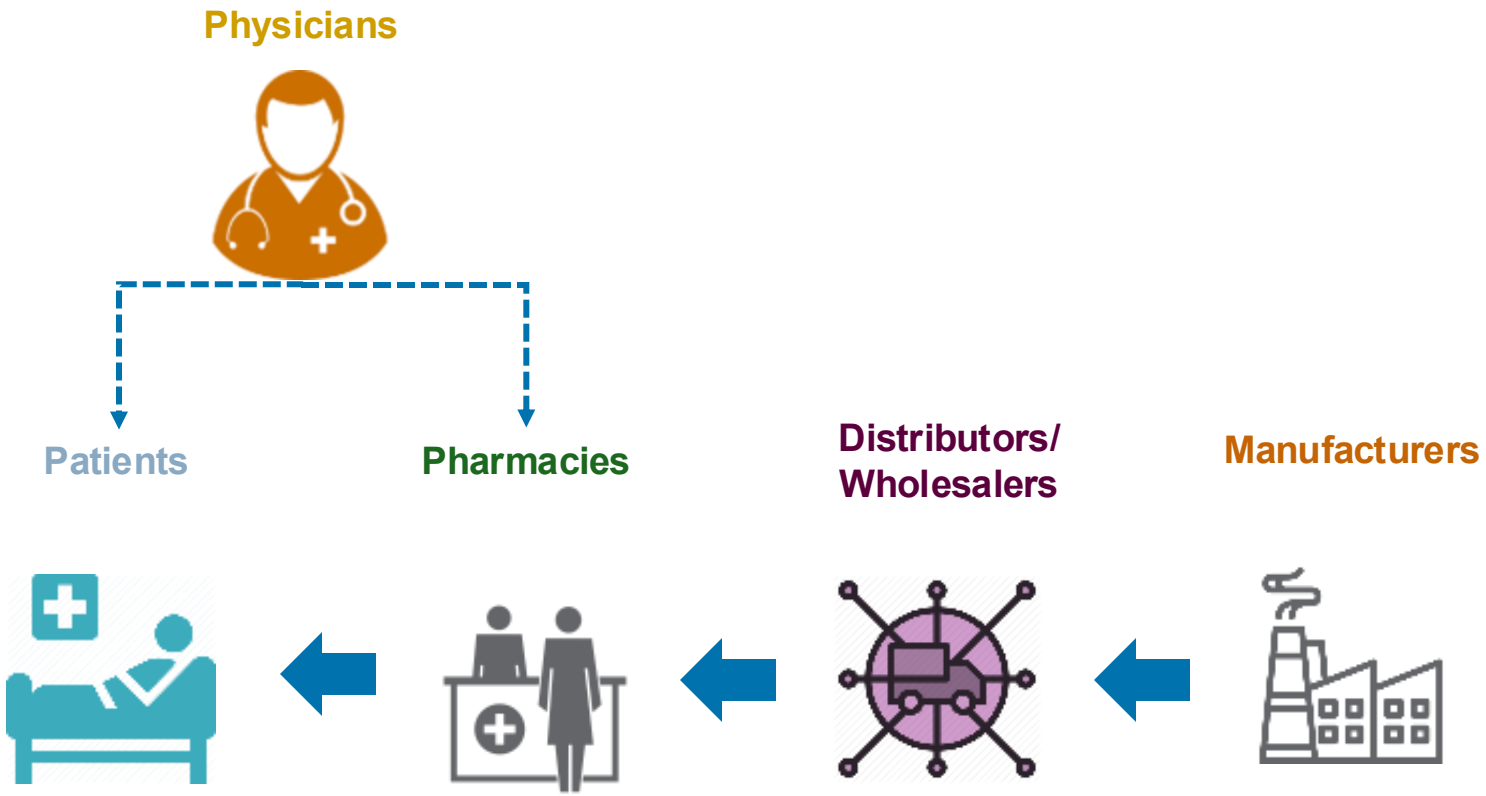
★ **State level:** Prescription Drug Affordability Boards

Today's Agenda:

Key policy changes at the state level, specifically **state prescription drug affordability boards (PDABs)**, designed to address the increasing costs of innovative products.

- **PDABs: Current Landscape and Future Trends**
- Implications for **Patient Affordability and Access**

Background: Flow of Products in the Pharmaceutical Industry



Product Flow

Prescription Flow

Background: Flow of Payments in the Pharmaceutical Industry

Physicians

- Reimbursed by health plans & patient cost sharing for visit costs

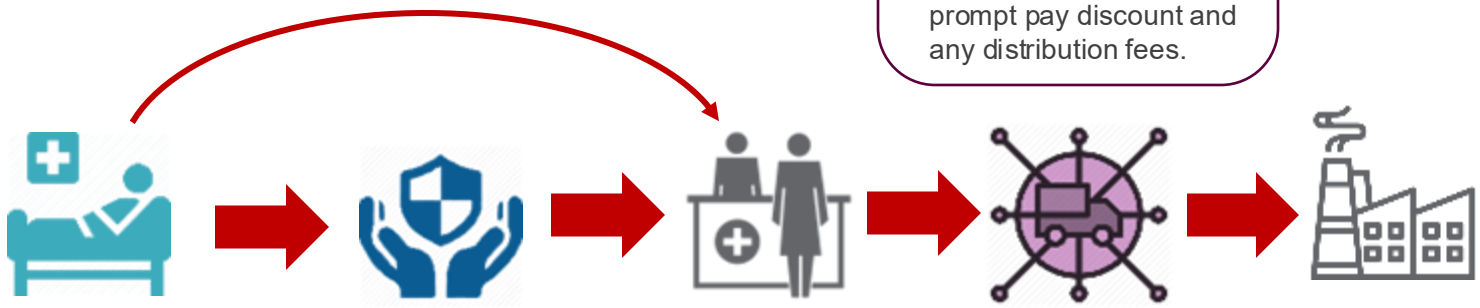
Insurers, Pharmacy Benefit Managers, and Government Health Plans

- Pay pharmacy pre-negotiated or administratively set price for covered patients
- May have an in-house mail-order pharmacy
- Negotiate rebates in exchange for formulary placement with **manufacturers**

Distributors / Wholesalers

- Pay manufacturers for product
- Provide and charge back manufacturer discounts to pharmacies
- Purchases product at WAC, typically less a prompt pay discount and any distribution fees.

Co-payments to Pharmacy



Patients

- Pays premium to insurer
- Pay cost-sharing (or full price) to pharmacy
- May receive manufacturer assistance towards payment (e.g., copay cards)

Pharmacies

- Pay wholesalers for product
- Receive discounts from manufacturers (including via wholesalers)

Manufacturers

- Set a wholesale price for the product
- Collect net price due to discounts and rebates

Payment Flow

Prescription Drug Affordability Boards: Who They Are

Prescription Drug Affordability Boards:

- **Independent state bodies** created by state legislation and appointed by the governor and other state officials (state representatives, AG, etc.).
- Made up of experts in healthcare economics who **analyze drug costs and suggest ways to lower state/consumer spending.**
- **First PDAB created in 2019** and the scope of their authority and objectives are **still evolving**.

Composition:

- **Voting Members:** Appointees with backgrounds in healthcare economics, clinical medicine, or pharmaceutical policy.
- **Advisory/Stakeholder Councils:** Many PDABs have non-voting councils that provide technical assistance and patient insights, but do not have official decision-making power. Often includes representatives from patient advocacy groups.

PDABs differ significantly between states in objectives, evaluation criteria, and scope.

Prescription Drug Affordability Boards: Stated Purpose

Affordability Reviews: Review cost of prescription drugs to assess affordability for patients and insurers.

- **Select Drugs for Affordability Review:** Involves consideration of numerous factors, including **drug pricing** (including patient out-of-pocket costs), publicly available data, and public/**patient input**.

Recommendations: Provide recommendations to state legislatures on strategies to reduce prescription drug spending.

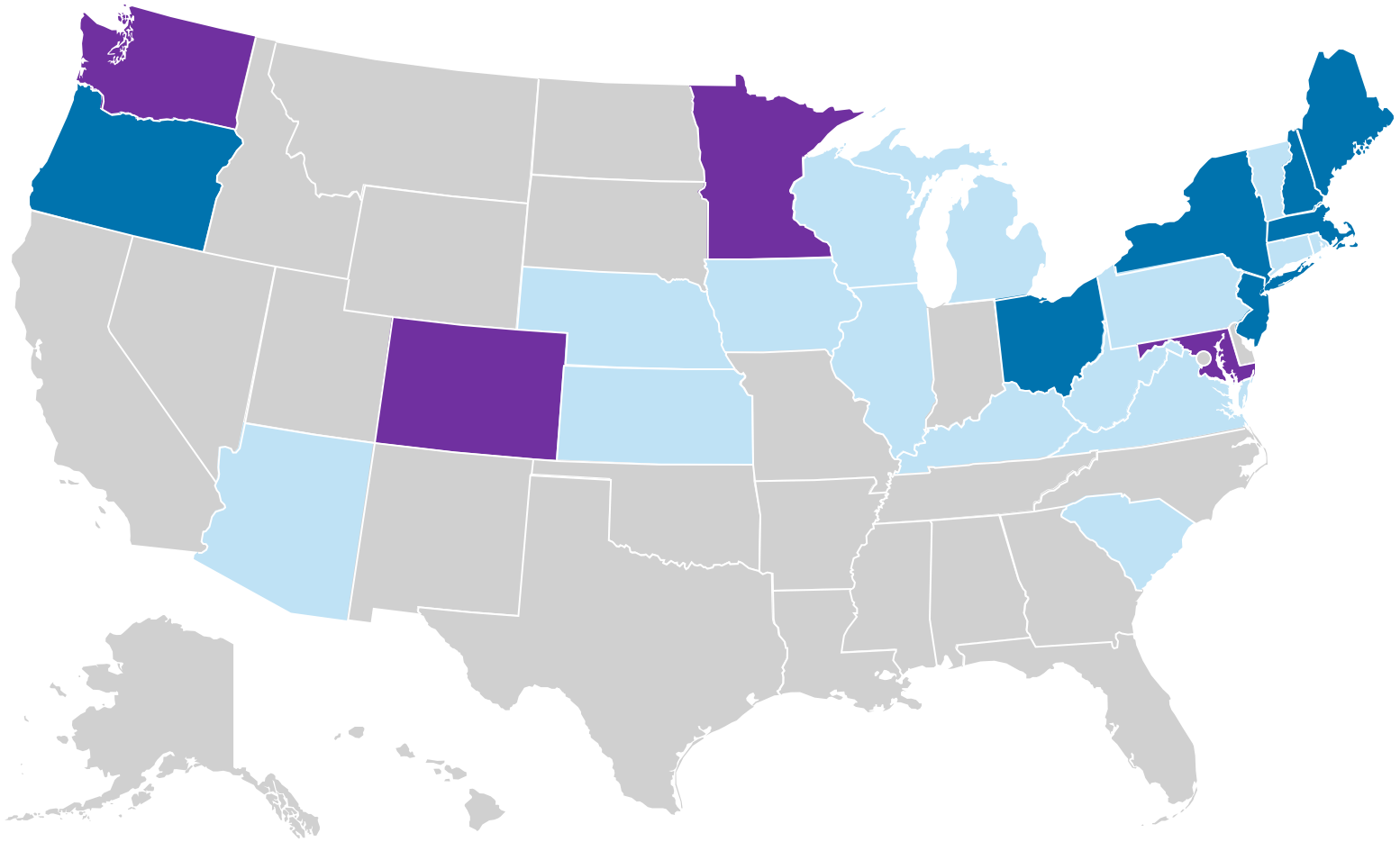
Negotiation: Engage in negotiations on prescription drug pricing with pharmaceutical companies, which may include negotiating Medicaid supplemental rebates.

Set Upper Payment Limits: Set reimbursement limits on what certain payers within a state will pay for selected medicines.

PDABs have significant discretion:

- Some enabling state legislation does not specify selection or review criteria.
- No states explicitly define "affordable" or "affordability challenge."

Prescription Drug Affordability Boards: Current Landscape*



- States with PDABs that can set upper payment limits
- States with PDABs
- States with legislative proposals to establish PDABs

*As of April 2025.

Source: Allmon, Tracy Baroni, Rebecca Roman, and Charlotte Hanby, "Prescription Drug Affordability Boards (PDABs)," Magnolia Market Access, March 25, 2025, https://www.magnoliamarketaccess.com/prescription-drug-affordability-boards-pdabs/.

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Prescription Drug Affordability Boards: Upper Payment Limits

Upper Payment Limits

Upper Payment Limits: Ceiling price on reimbursement for selected drugs.

Where: Colorado, Maryland,** Minnesota, and Washington (Oregon***)

Application: All consumers in the state*

Number of Drugs: Up to 12 drugs/yr (Colorado can select up to 18 drugs)

"High Cost" Drugs

"High Cost" Drugs (Colorado/Maryland):

- Branded drugs with a Wholesale Acquisition Cost (WAC) of $30,000+/year

Litigation

Litigation challenging the constitutionality of the Colorado PDAB and the authority to set UPLs was **recently dismissed**

PDABs are likely to face **continued litigation,** especially once states begin **setting UPLs**

Dismissal of the case is likely to **encourage more legislative activity around PDABs**

*Excluding enrollees in self-funded plans that elect not to participate. **Legislation pending to expand UPL to all consumers in the state.
***Oregon PDAB submitted report in November 2024 on potential approaches and methodologies for establishing UPLs.

Prescription Drug Affordability Boards: Selected Drugs

Colorado

- **Enbrel** (Rheumatoid Arthritis)
- **Cosentyx** (Psoriatic Arthritis)
- **Stelara** (Crohn's)
- **Genvoya** (HIV)
- **Trikafta** (Cystic Fibrosis)*

*Rare disease drug

Maryland

- **Skyrizi** (Plaque Psoriasis)
- **Farxiga** (Diabetes)
- **Jardiance** (Diabetes)
- **Ozempic** (Diabetes)
- **Trulicity** (Diabetes)
- **Biktarvy** (HIV)
- **Dupixent** (Asthma)
- **Vyvanse** (ADHD)

Patient Impacts

Selected therapeutic areas include **autoimmune diseases, diabetes,** and **HIV.**

Some states exempt **rare disease drugs** from affordability review, given the concerns over patient access to treatment.

PDAB Economics: Patient Affordability and Access

Affordability Concerns for Patients

Unless the PDAB imposes limits on patient out-of-pocket (OOP) payments, **patients may not realize the savings associated with UPLs**.

For patients to realize the savings associated with UPLs:

- Patient's OOP payments must be based on UPL (depends on patient's plan)
- Patient's PBM would have to move the drug with a UPL to a lower formulary tier with a reduced OOP burden (depends on patient's formulary)

Access Concerns for Patients

Access Today:

Given the complexity of the pharmaceutical supply chain, there a **risk that patients would not have access** to selected drugs.

- If a retail pharmacy's distributor/wholesaler is located out of state, will they be able to purchase the drug at the UPL?
- If a drug is physician administered, will physicians be able to purchase these drugs at discounted prices through "buy and bill"?

Access Tomorrow:

- How will **innovation** in therapeutic areas, especially in **rare disease**, selected for UPLs be impacted?

Prescription Drug Affordability Boards: Conclusion

Takeaways

PDABs differ significantly between states in objectives, evaluation criteria, and scope.

PDABs have significant discretion over the selected drugs and review process.

Upper Payment Limits

There is **significant uncertainty surrounding UPLs**

Litigation

- It is **very likely that UPLs will face litigation**, but it is unclear whether UPLs will survive litigation.

Patient Impact

- It is unclear whether a UPL will reduce patients' OOP.
- UPLs have the potential to **impact patient access today** and could **impact future innovation** within a therapeutic area, especially in **rare disease**.

Thank You.

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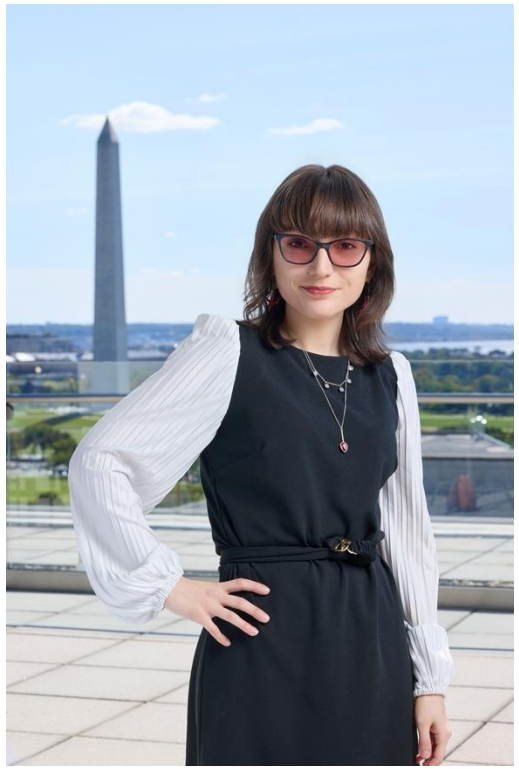

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