The Inflation Reduction Act One Year Later

Where Are We Now? What Other Challenges are on the Horizon?

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Today's Discussion

I. Inflation Reduction Act (IRA)

- *Latest on Medicare "Negotiation"*
- *Upcoming Redesign of Medicare Part D*
- *Impacts of IRA*
- *Litigation*

II. Broader Environment

- *Proposed Changes to Medicaid Drug Rebate Program*
- *Emergence of State Prescription Drug "Affordability" Boards*
- *Other Challenges*

Questions Today That Aren't Answered?

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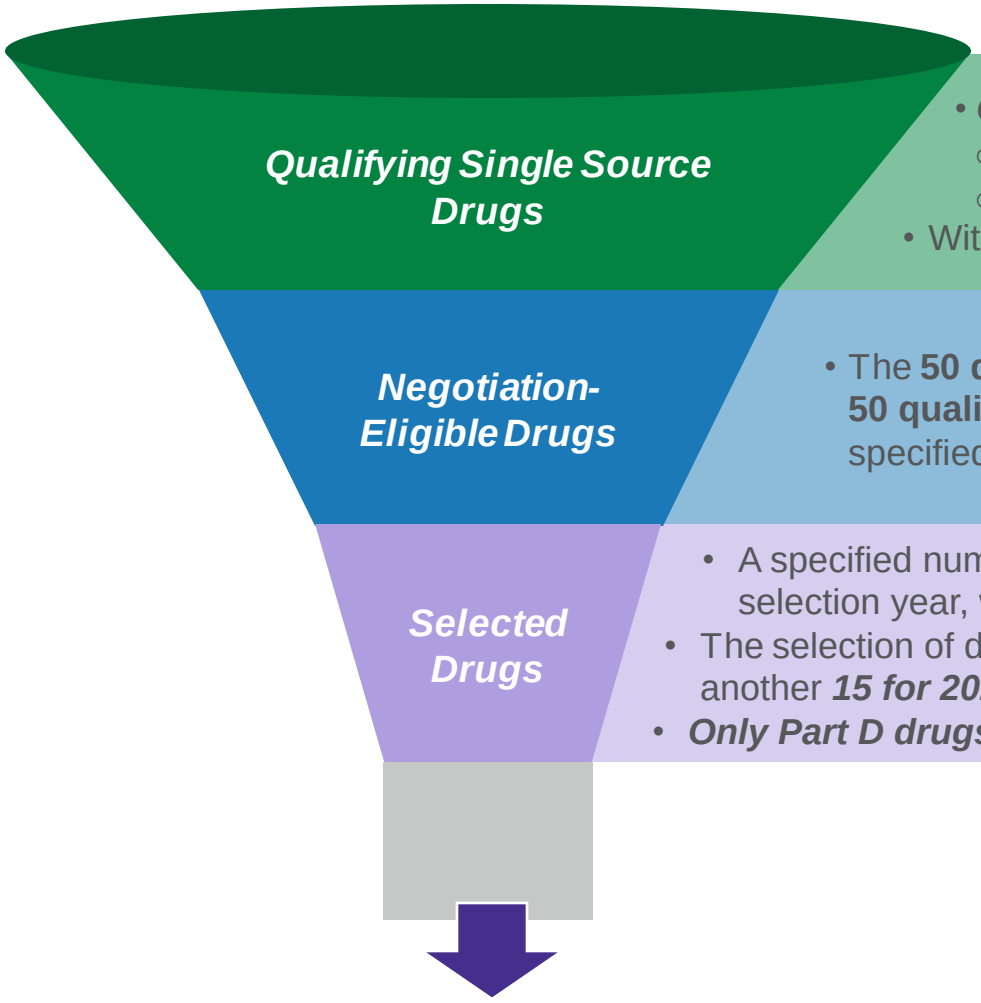
Inflation Reduction Act (IRA)

-Latest on Medicare "Negotiation"

- Upcoming Redesign of Medicare Part D

- IRA Impacts

Recap: Drugs Subject to Medicare Negotiation



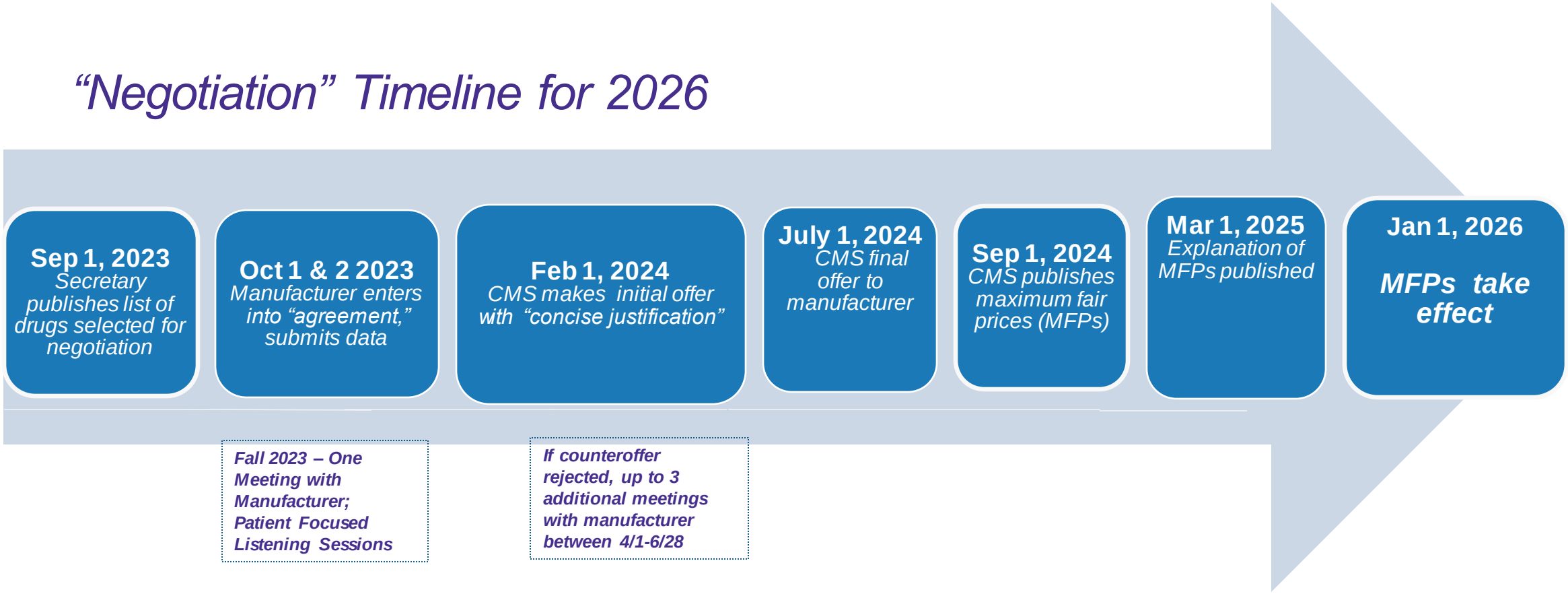
- ***Certain drugs/biologics approved/licensed by FDA:***
  - ***Drugs at least 7 years post-approval*** by the selection date
  - ***Biologics at least 11 years post-licensure*** by the selection date
- With ***no generic/biosimilar on the market*** (an "authorized generic drug" does not count)

- The **50 qualifying single source drugs with highest total expenditures under Part D** and the **50 qualifying single source drugs with highest total expenditures under Part B** during a specified 12-month lookback period.

- A specified number **of the highest ranked negotiation-eligible drugs**, published by February 1 of the selection year, which is two years before the initial price applicability year:
- The selection of drugs for negotiation is ***cumulative***: The Secretary must select ***10 drugs for 2026***, another ***15 for 2027***, another ***15 for 2028***, and another ***20 for 2029 and each year thereafter***
- ***Only Part D drugs may be selected for 2026 and 2027***

Key Dates – IRA Implementation

"Negotiation" Timeline for 2026



The timeline for initial price applicability years after 2026: selected drugs published Feb 1; enter into agreement Feb 28; manufacturer submission Mar 1; initial offer June 1; negotiation ends Nov 1; MFP published Nov 30th.

Medicare "Negotiation" – Key Issues

- ✓ **Drug selection process outlined by the Centers for Medicare & Medicaid Services (CMS) largely finalized without public input**
  - CMS combining drugs with same active moiety/active ingredient for selection purposes (should instead be at NDA/BLA level)
  - Limited exception for orphan drugs
- ✓ **CMS's troubling "bona fide" marketing standard** for generics and biosimilars
- ✓ **Uncertainty and lack of transparency in how CMS will review/assess evidence** in setting the maximum fair price (MFP)
- ✓ **Uncertainty in "operationalization" of the MFP** and preventing duplicate discounts
- ✓ Lack of clarity in how CMS will **protect patient access** to needed medicines in Medicare Part D

Medicare Part D – Key Changes

- **Beneficiary 5% cost sharing in catastrophic phase eliminated starting in 2024**, after beneficiaries reach the OOP threshold
- **Beneficiary OOP threshold lowered to $2,000 starting in 2025**, increased annually by an inflation factor. Beneficiaries will be able to spread these costs throughout the year through the Medicare Prescription Payment Plan or (MPPP)
  - OOP cap/payment plan ("smoothing") longstanding BIO priority

Overview Medicare Part D Benefit Restructure

Current Structure (2022)	New Structure (2025)
Deductible 100% beneficiary	**Deductible** 100% beneficiary
Initial Coverage Phase 25% beneficiary 75% plan	**Initial Coverage Phase** 25% beneficiary 65% plan **10% drug company***
Coverage Gap 25% beneficiary 5% plan 70% drug company	**Coverage Gap** **ELIMINATED**
Catastrophic Phase 5% beneficiary 80% govt 15% plan	**Catastrophic Phase** 0% beneficiary 20% government (or 40% where drug not subject to discount program) 60% plan **20% drug company***

**Generic drugs and drugs subject to Medicare negotiation are exempt from 10%/20% obligation*

Part D Redesign– Key Issues

- ✓ **Increased plan liability to 60% in catastrophic will result in increased use of Utilization Management -** how will CMS respond and oversee?
- ✓ CMS has said it will intensify formulary review but there is **uncertainty and lack of transparency in how CMS will actually do this.**
- ✓ **Will Medicare beneficiaries understand the new "MPPP" and take advantage of it?**

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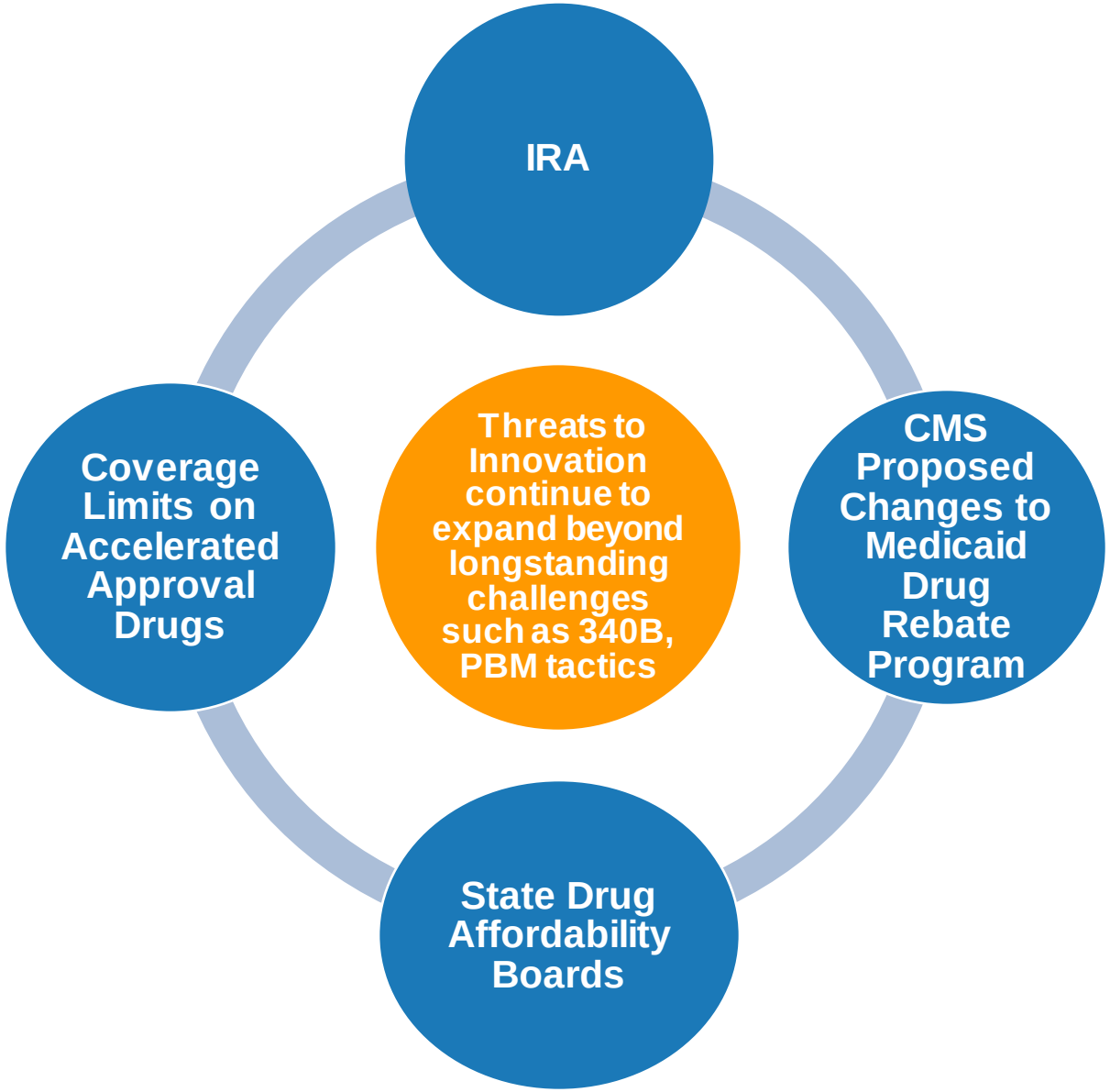
Broader Environment

- Proposed Changes to Medicaid Drug Rebate Program

- Emergence of State Prescription Drug "Affordability" Boards

- Other Challenges

Challenges Extend beyond IRA



Medicaid "Misclassification" Rule and BIO Strategy

Under the guise of "technical changes" CMS has proposed to upend more than 30 years of historical and legal precedent under the Medicaid Drug Rebate Program (MDRP). Specifically, CMS proposes to:

- **Materially Change the Definition of Best Price to require aggregation ("stacking")** of discounts paid to all entities throughout the supply chain rather than the discount paid to any single entity; proposed policy would also impact the ceiling price for 340B
- **Expand Covered Outpatient Drugs (CODs) to include bundled drugs** (if itemized), such as those delivered in the inpatient hospital setting, thereby expanding the universe of drugs subject to Medicaid rebates and also potentially expanding drugs subject to 340B discounts
- **Subject "therapeutic vaccines" to rebates** under the MDRP (preventive vaccines would still be exempt from rebates)
- **Impose vast new reporting obligations ("verification survey")** aimed at collecting a wide range of new information that mirror the information that CMS is collecting for the new "negotiation" program in Medicare – with a specific focus on cell and gene therapies

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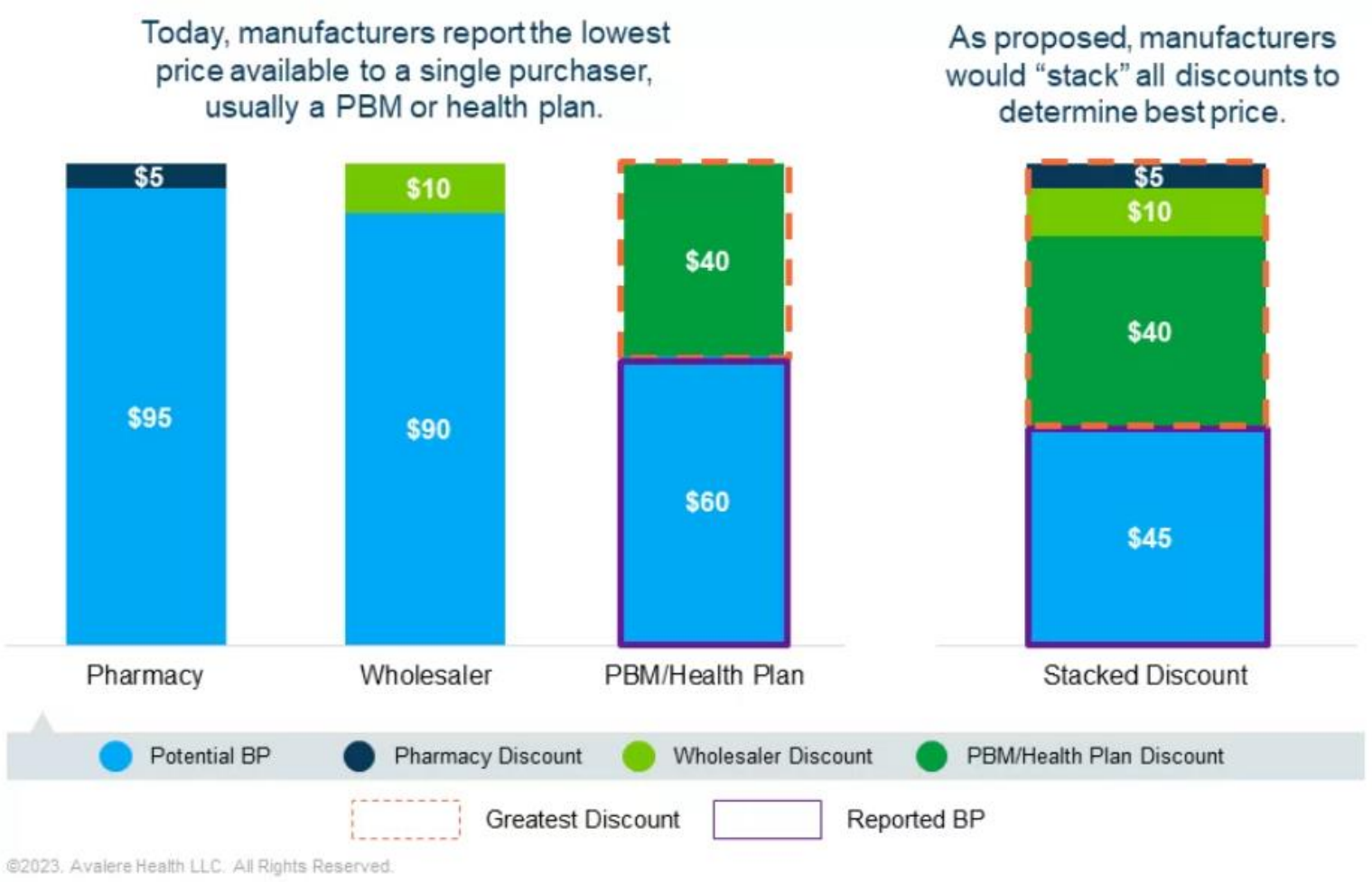
“Stacking” Impact

Figure 1. Illustration of Best Price Determination for a $100 Drug



Source: Avalere July 26, 2023, “CMS Best Price Discount Stacking Proposal May Trigger AMP Cap”

Drug Pricing Legislation and the States: 25 states have passed 40 bills addressing drug pricing in 2023, ranging from launching studies, to increased transparency on pricing, to funding and empowering price review boards

State Bills in 2023 Adopted into Law			
State	Initiative	Category	Description
AZ	SB 1382	PBM	PBMs will require certification
AR	HB 1481	PBM	PBM rebate calculation changes
	SB 94	PBM	State information gathering on PBM rebate financials
CA	SB 101	Cost Sharing	Funds biosimilar insulin
CO	HB 23-1225	Price Review	Expands price review board to 18 drugs, drugs with a launch price of over $3,000, or an avg yearly cost of $30,000 or more, or drugs with a 200% or $300 increase in the last 12 months
	HB 1002	Cost Sharing	$60 price cap for epi-pens
	HB 23-1201	PBM	Caps PBM charges for prescription drugs to what the pharmacy cost of the drug is
	SB 23-195	PBM	Requires PBMs to include cost sharing paid by the insured in the cost sharing requirement
CT	CT HB 6669	Cost Sharing	Establishes a drug discount card and authorizes the state to pool with other states to lower drug prices
DE	HB 54	Cost Sharing	Requires epi pens to be available on the lowest tier of pharmacy
FL	SB 2500	Importation	Authorizes $15M to pay for drug importation from Canada
	SB 1550	Transparency	Requires pass through pricing for PBMs and bans gag clauses, also requires disclosures by manufacturers on price increases and patent extensions
	SB 2502	Cost Sharing	Requires competitive procurement of biologics, including but not limited to insulin and epi-pens
IN	SB 8	Cost Sharing	Cost sharing to be calculated at sale, requires pass through pricing
IA	HF 423	PBM	Bans discrimination by PBMs
ME	LD 1395	Transparency	Additional data collection on 340B programs
MD	HB 200/SB 181	Price Review	Provides $1.5M in funding for the drug affordability review board
	HB 279/SB 202	Price Review	Enables the drug affordability review board to set a maximum price
	HB 382	Transparency	Information gathering on payments in 2021 and 2022 for the drug affordability board
MN	SF 2744	Price Review	Creates a price review board that can establish upper price limits for drugs costing $60,000 per year, or with a greater than $3,000 price increase.
	SF 2995	Transparency	Strengthens existing drug transparency laws
NV	AB 434	PBM	Prohibits discrimination against 340B programs
NM	SB 51	Cost Sharing	Third party payments on behalf of an enrolled plan member count towards the plan member's cost sharing
NY	A 2200/S 836	PBM	Requires PBMs to provide certain data at the request of an insured member
ND	HB 1413	Cost Sharing	Study on the impact of third party payers on drug costs
	SB 2140	Cost Sharing	Caps price of 30 days of insulin at $25
	SB 2378	PBM	Prohibits PBMs from limiting insured choices regarding pharmacy and physician
OR	SB 608	Transparency	Survey on the cost of dispensing drugs
RI	SB 871	Cost Sharing	Caps coinsurance on speciality drugs at $150 per 30 day supply
SC	S 520	PBM	Prohibits PBMs from being anti-competitive or restricting use of in-network pharmacies
SD	HB 1135	PBM	Requires PBM licensing
TX	HB 999	Cost Sharing	Third party payments on behalf of an enrolled plan member count towards the plan member's cost sharing
	HB 25	Importation	Establishes and requires Texas to seek certification for a drug importation program
	HB 4611	PBM	Establishes audits of PBMs
	HB 4990/SB 2402	PBM	Establishes bulk state purchasing of drugs for certain government employees and dependents
	SB 622	Transparency	Requires PBMs to provide certain data at the request of an insured member
UT	SB 193	PBM	Bans dispensing of physician administered drugs directly to patients
VA	HB 1471	PBM	Require PBMs to provide real time cost information to enrollees
WV	SB 577	Cost Sharing	Caps price of 30 days of insulin at $35 and for devices at $100
WY	SF 151	PBM	Bans PBMs from preventing pharmacies from filing batch appeal denials

Source: RBC Capital Markets, NASHP

Prescription Drug Affordability Boards (PDABs)

- State created boards to address prescription drug costs by establishing an "upper payment limit" **(notably, these boards do not address patient out-of-pocket costs)**
- Charged with identifying high-cost therapies relative to the value – **targeting some of the most innovative therapies and patients with limited treatment options**
- May rely on 3rd party health-value assessment entities like ICER to determine the value of therapies – **ICER advances troubling, discriminatory tools such as use of "QALYs"**
- **Colorado** is furthest along in implementation

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QUESTIONS?