

# Apexus PVP and 340B Market Update

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340B Midwest Regional Conference & Expo  
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DISCLOSURE  
STATEMENT

Christopher Hatwig has no relevant financial relationship(s) with ineligible companies to disclose.

*and*

None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.





**LEARNING  
OBJECTIVES**

At the completion of this activity, the participant will be able to:

- Describe the key drivers of 340B program growth over the last 5 years
- Recognize primary challenges of contract pharmacy restrictions and mitigation strategies employed by covered entities
- Discuss options for improving transparency and the integrity of the 340B program





HRSA, Covered entities, manufacturers, and the PVP work together to lower drug prices and improve drug access





# Prime Vendor Focus

**340B**  
Prime Vendor  
PROGRAM™

Sourcing Operations – Contracting, Distribution,  
and Manufacturer Refund Services



Education and Training

**Apexus**  
Answers  
CALL CENTER

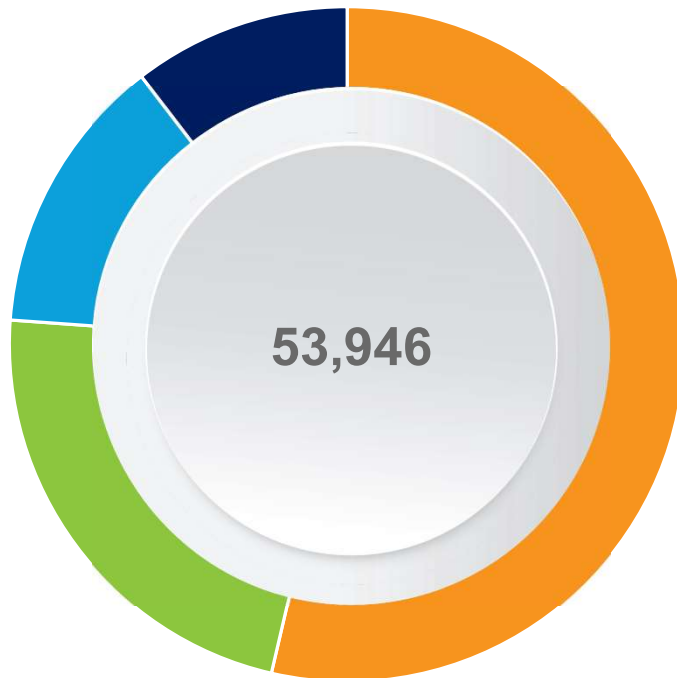
HRSA-Aligned National Call Center

340B  
Midwest Regional  
Conference & Expo



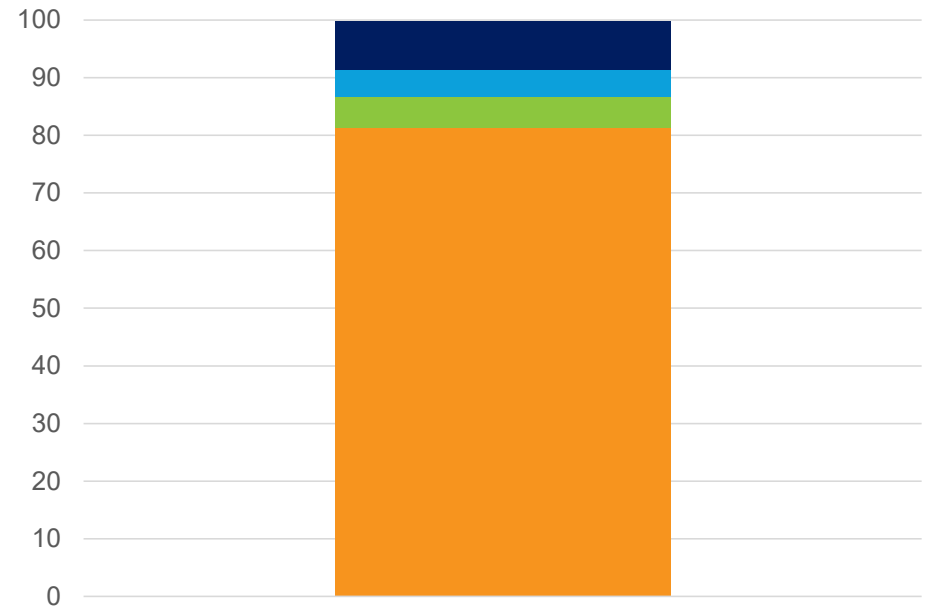
# 340B Covered Entities

Registrations as of August 2024

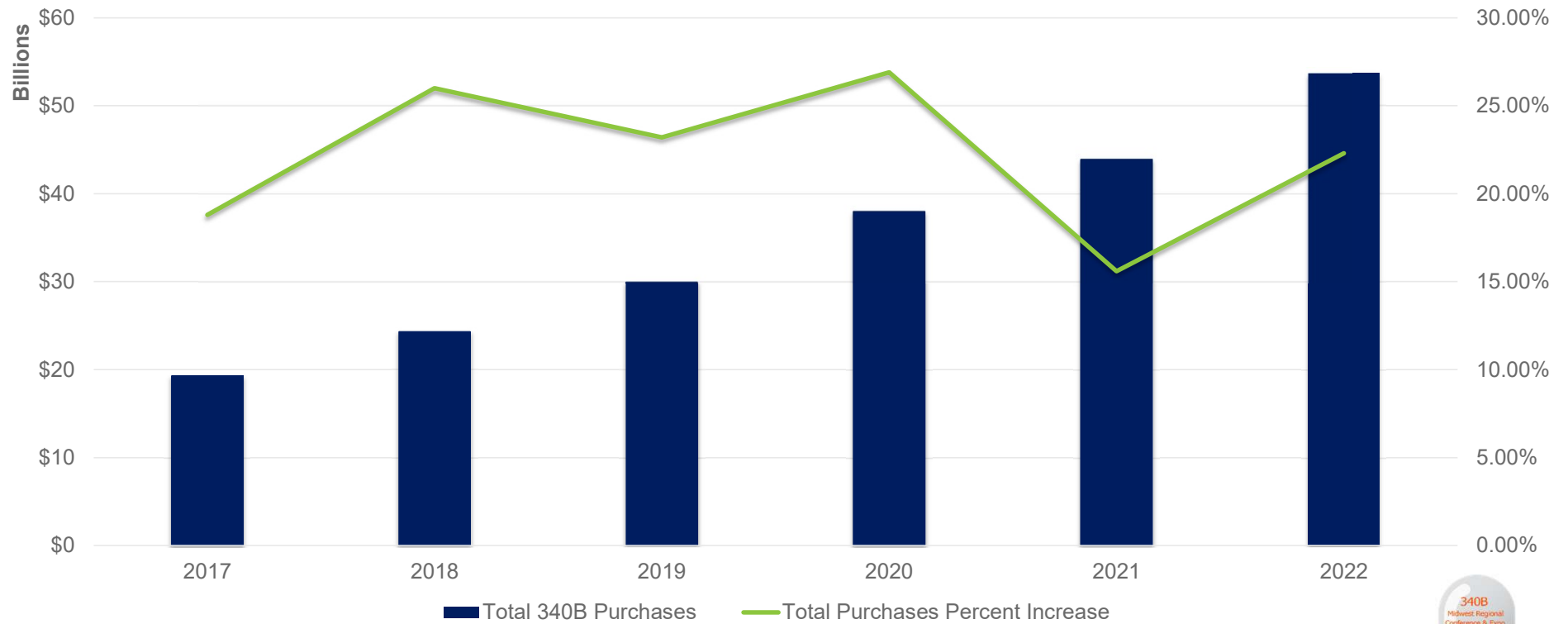


- GPO-Prohibition Hospitals
- Health Centers
- Orphan Drug Exclusion Hospitals
- Grantees

Percent of Total 340B Spend by CE Type



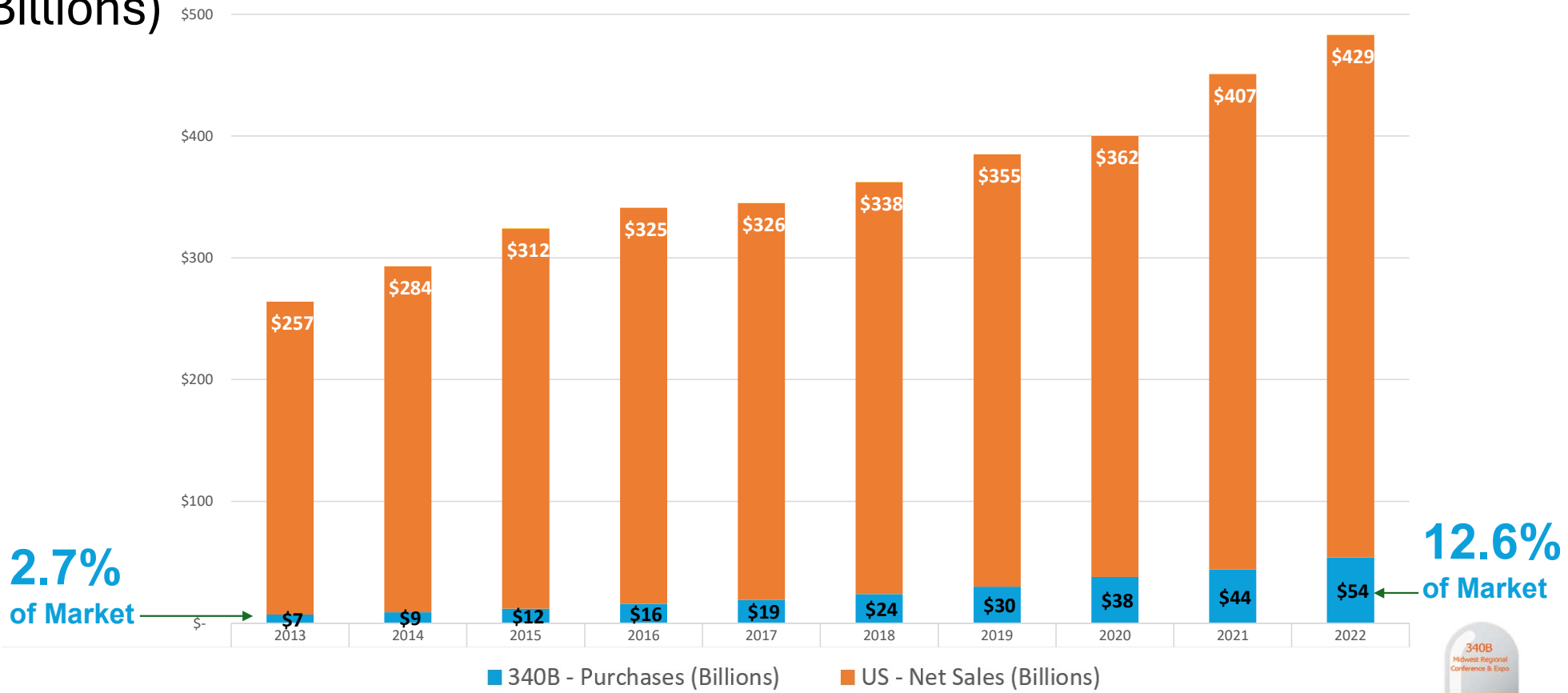
# 340B Program Growth





# 340B within the US Market – Net Sales

(Billions)



# Identify the Contributors for 340B Program Growth



Shift to  
outpatient care



Increase in  
new drug  
launch prices



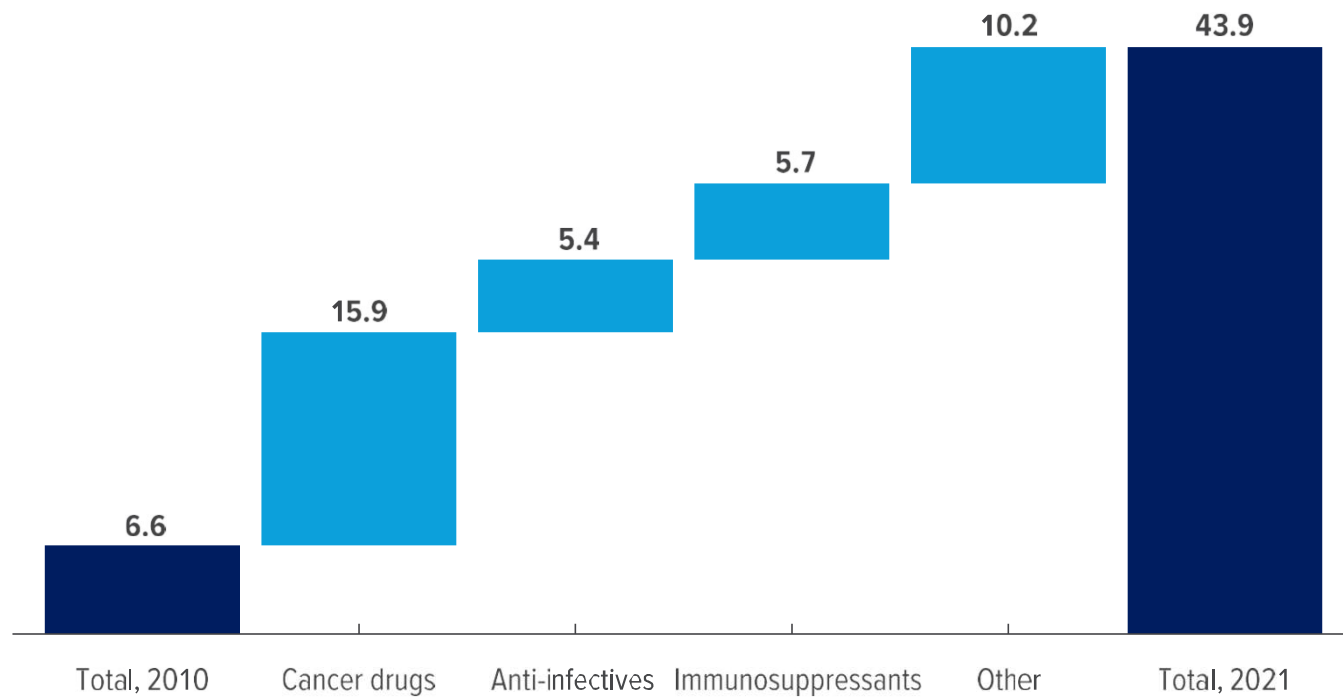
Innovative therapies

- Cancer
- Immunology
- Infectious diseases (HIV)



# Growth in Spending, by Drug Class, 2010 to 2021

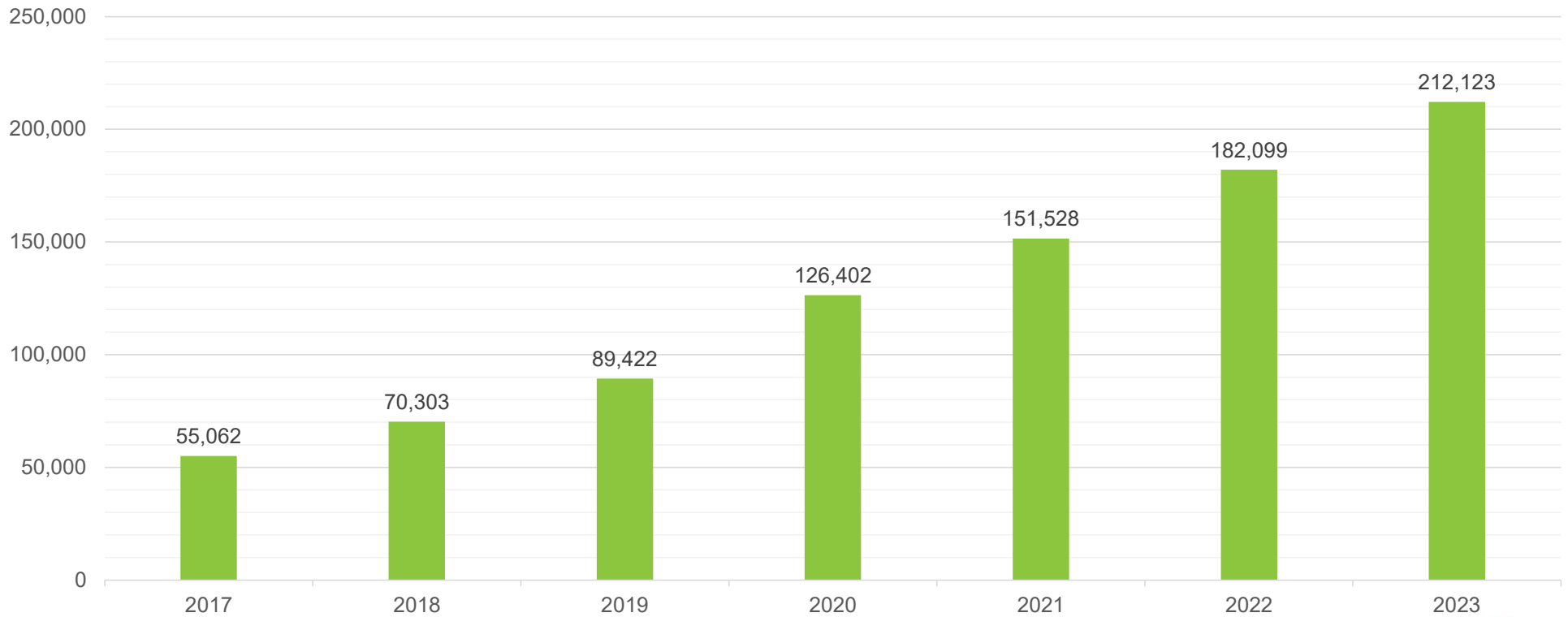
(Billions of Dollars)



Seventy-three percent of the growth in 340B spending from 2010 to 2021 can be attributed to spending on cancer drugs, anti-infectives, and immunosuppressants.



# Contract Pharmacy Registrations



# 340B Marketplace Influences



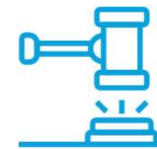
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Drug pricing  
disruption



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Contract  
pharmacy turmoil



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Challenges to  
HRSA Guidance



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Federal 340B  
proposals



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State involvement  
in 340B





# 340B Ceiling Price Influences

$$\text{AMP} - \text{URA} = \text{340B Ceiling Price}$$



## Average Manufacturer Price (AMP)

The weighted average price paid (net of discounts) for drugs sold to retail community pharmacies



## Unit Rebate Amount (URA)

**Brand:** Greater of [(AMP × 23.1%) or (AMP – BP)] **plus** inflation penalty

**Generic/OTC:** 13% of AMP **plus** inflation penalty



## Best Price (BP)

Lowest price to US customers (including MFP); certain federal pricing, such as 340B, excluded



## Inflation Penalty

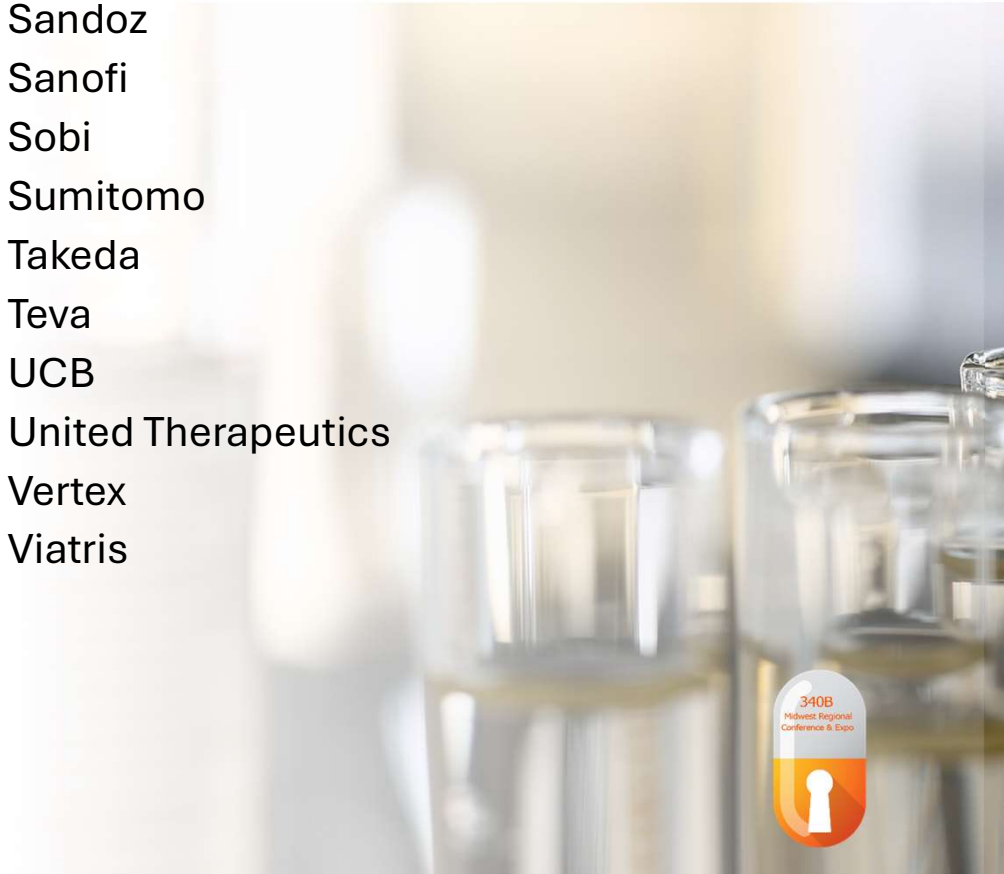
Cumulative amount of commercial price increases above inflation over the life of the product



# 37 MFRs with CP Restrictions (as of 8/27/24)



AbbVie	EMD Serono	Pfizer
Alkermes	Exelixis	Sandoz
Amgen	Genentech	Sanofi
Astellas	Gilead	Sobi
AstraZeneca	GSK	Sumitomo
Bausch Health	Incyte	Takeda
Bausch + Lomb	Jazz	Teva
Bayer	Johnson & Johnson	UCB
Biogen	Liquidia	United Therapeutics
Boehringer Ingelheim	Merck	Vertex
Bristol Myers Squibb	Novartis	Viatrix
Eisai	Novo Nordisk	
Eli Lilly	Organon	



# HRSA Challenges



**Orphan Drug  
Exclusion**

**Contract  
Pharmacy**

**Patient  
Definition**

**OPAIS  
registration**

**Audit  
Findings**





# Federal 340B Proposals



SUSTAIN  
Act

340B  
PATIENTS  
Act

ACCESS  
340B

340C



# State Activity around 340B

- State PBM 340B Discriminatory Contracting Laws
- State 340B Contract Pharmacy Laws (and Litigation)
- State 340B Covered Entity Reporting Transparency Laws

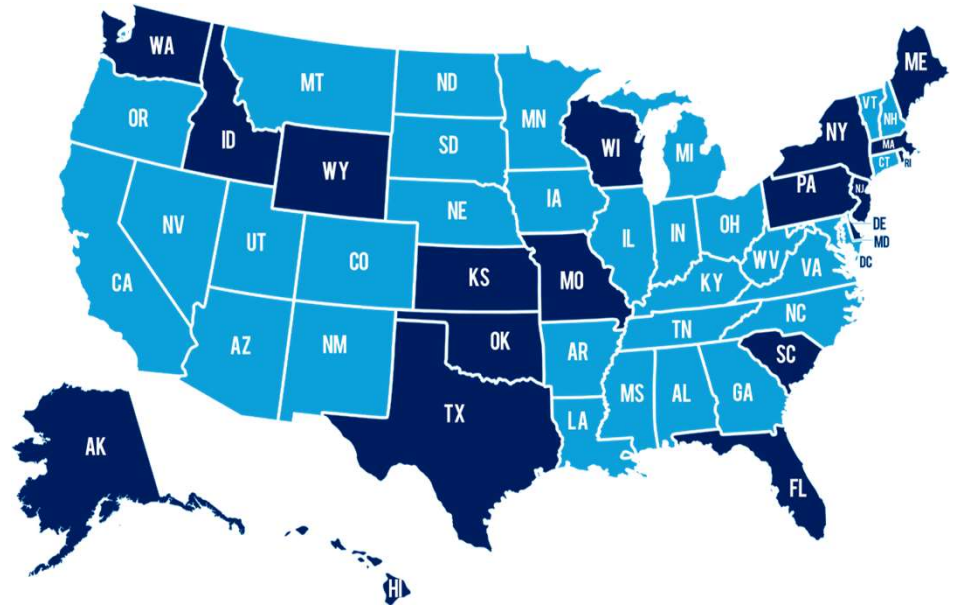


# PBM/340B Anti-Discriminatory State Policies

As of Aug 27, 2024

- |                    |                          |                           |
|--------------------|--------------------------|---------------------------|
| 1. <b>Alabama</b>  | 11. Kentucky             | 21. <b>New Mexico</b>     |
| 2. <b>Arizona</b>  | 12. Louisiana            | 22. <b>North Carolina</b> |
| 3. <b>Arkansas</b> | 13. Maryland             | 23. North Dakota          |
| 4. California      | 14. <b>Michigan</b>      | 24. Ohio                  |
| 5. Colorado        | 15. <b>Minnesota</b>     | 25. <b>Oregon</b>         |
| 6. Connecticut     | 16. Mississippi          | 26. South Dakota          |
| 7. <b>Georgia</b>  | 17. <b>Montana</b>       | 27. <b>Tennessee</b>      |
| 8. Illinois        | 18. <b>Nebraska</b>      | 28. <b>Utah</b>           |
| 9. Indiana         | 19. Nevada               | 29. Vermont               |
| 10. Iowa           | 20. <b>New Hampshire</b> | 30. <b>Virginia</b>       |
|                    |                          | 31. <b>West Virginia</b>  |

**Bold** = State requires licensure or registration of PBM (n=20)



Light blue = 340B anti-discriminatory state policy enacted

Dark blue = no 340B anti-discriminatory state policy enacted



# Contract Pharmacy Protection State Laws

19

Others Proposed

- Arkansas (Act 1103)
- Louisiana (Act 358)
- West Virginia (SB 325)
- Mississippi (HB 728)
- Kansas (SB 28)
- Maryland (HB 1056)
- Minnesota (HF 4757)
- Missouri (SB 751)



# State 340B Reporting Requirements

## Passed Legislation

- Minnesota (SF 2995)
- Maine (LD 2995)
- Washington (SB 5187)
- Michigan Medicaid – Agency Policy

## Proposed Legislation

- Connecticut (SB 241)
- Indiana (SB 168)



# Key Stakeholder Groups Diverse Positions in the Market



## Manufacturers

- Transparency
- Stacked discounts
- CP/PBMs profiting on the program's discounts
- Patients aren't receiving value of savings



## Covered Entity

- Financial pressures
- Reimbursement concerns
- Intent of program



## HRSA

- Program Integrity
- ADR
- Education
- Transparency

# PVP Aligning to Stakeholder Needs



## HRSA support

- 340B data analytics
- Technical Assistance
- Marketplace trending, impact analysis and assessment



## Working with distributors to enhance access

- Understanding and contracting with alternate distribution networks
- Collaborating with distributors to make access to restricted products easier



## Deepening relationships with suppliers

- Manufacturer-specific education
- Increasing number of manufacturers with whom we have relationships
- New approaches to contracting



## Customized education by covered entity type

- Working directly with NACHC and PCAs
- Segmentation of learning by covered entity type, role, level of learning



# Neutrality More Important Than Ever

## Critical roles of PVP



Neutral third party to support all stakeholders



Trusted resource aligned with HRSA



Focus on 340B Program integrity







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