



## **340B Compliance and Strategy** Navigating Challenges in a Shifting Landscape



# Agenda

1. 340B Program Overview
2. 340B Program Strategy
3. Manufacturer Barriers
4. 340B Program Outlook



# 01

## 340B Program Overview



# 340B Drug Pricing Program Overview

Part of the Public Health Services Act,  
section 340B & Medicaid rebate program

Federally mandated drug pricing program created in 1992

- Expanded under the Clinton, W. Bush and Obama administrations

Requires drug manufacturers to provide front-end discounts on covered **outpatient drugs** to help **stretch scarce federal resources** at covered entities that **serve vulnerable and indigent populations**

# Diversion

Drugs can only be used on an outpatient basis for a covered entity's patients as defined by HRSA - **use for other individuals constitutes prohibited diversion**

## What is a covered entity?

- Where services are provided
- Physicians must be employed or under a contractual or other arrangement
- Entity should maintain a listing of approved 340B physicians

## Who is an eligible patient?

- Individual with whom the entity has an established relationship such that they maintain medical records
- Individual receiving care at an eligible location from an eligible provider

# Patient Definition

## Patient Eligibility in a **CHC** Setting

Outpatient at the time of drug administration

Receive the drug at a location that is within the scope of the qualifying grant

Receive the care from an employed or contract clinician

Have a record with the covered entity providing the care

## Patient Eligibility in a **Retail Pharmacy** Setting

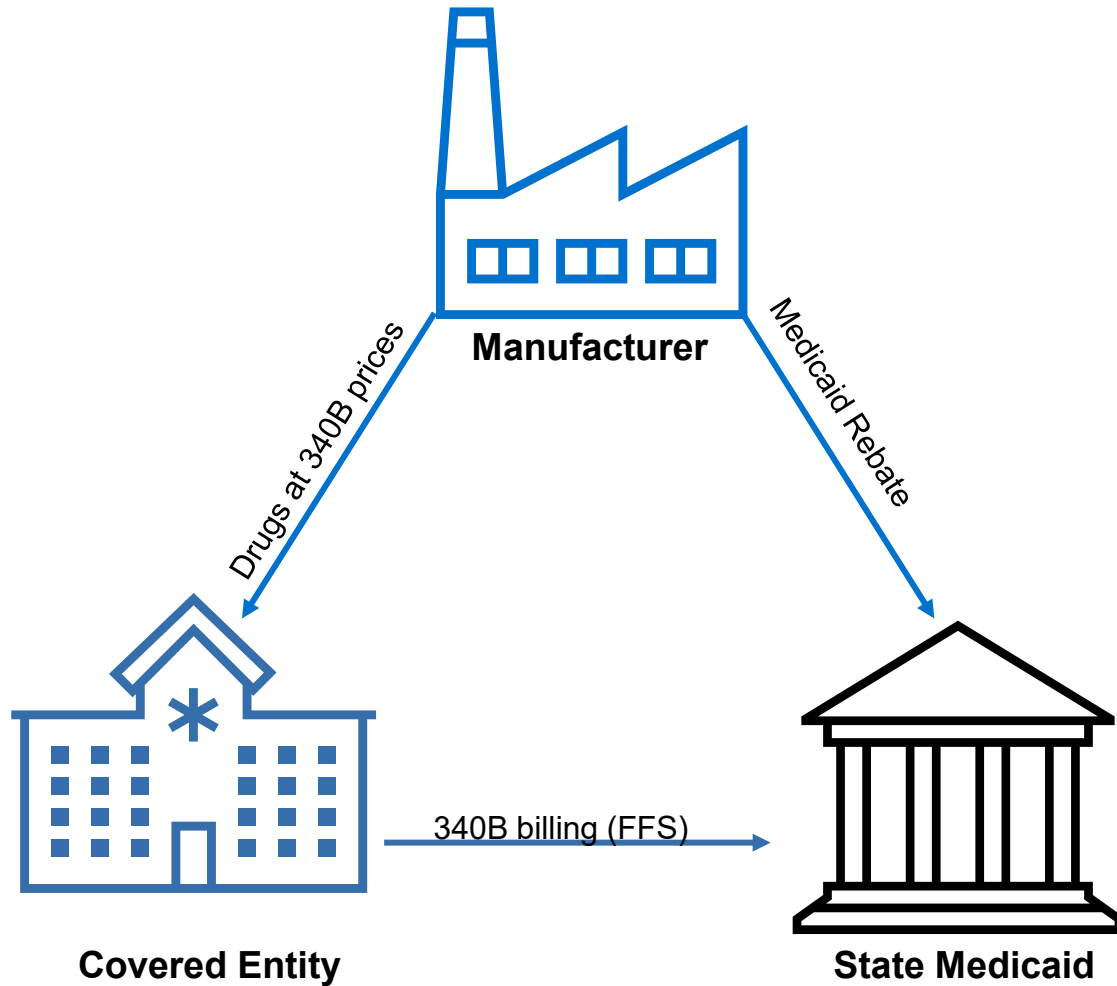
Have received care at a location that is within the scope of the qualifying grant

The drug must be related to the care provided by the grantee / CHC

Receive the care from an employed or contract clinician

Have a record with the covered entity providing the care

# Duplicate Discount



- 340B laws prohibit application of both 340B price discount on front end & payment of pharmacy rebate to state Medicaid on back end for same drug claim
- Some states have been slow to establish & communicate Medicaid billing requirements & potential modifiers
- Transition to Medicaid managed care has created confusion
  - Covered entities should have mechanisms in place to identify Medicaid Managed Care (MCO)

The responsibility for avoiding duplicate discount rests on the covered entity



# HRSA Audits



Results are made publicly available



Conducted by the Bizzell Group



Initially had an educational tone, but have since turned punitive with the introduction of penalties for non-compliance



Focus on contract pharmacy arrangements, diversion, duplicate discounts, & database records

## YTD FY23 Statistics

---

- Results posted for 152 audits (as of October 28, 2024)
- 90 audits resulting in Corrective Action Plans
- 39 audits resulting in manufacturer repayment
- Audits occurred in 39 states



# HRSA Audits



Results are made publicly available



Conducted by the Bizzell Group



Initially had an educational tone, but have since turned punitive with the introduction of penalties for non-compliance



Focus on contract pharmacy arrangements, diversion, duplicate discounts, & database records

## YTD FY24 Statistics

---

- Results posted for 74 audits (as of October 28, 2024)
- 15 audits resulting in Corrective Action Plans
- 11 audits resulting in manufacturer repayment
- Audits occurred in 36 states

# Manufacturer Audits

May only conduct  
after showing  
“reasonable  
cause”

Manufacturer  
inquiries to  
covered  
entities may  
help support  
“reasonable  
cause”

Important for  
covered entities  
to respond to  
manufacturer  
inquiries, failure  
to respond could  
result in audit

Details are not  
publicly available

# 02

## 340B Program Strategy



# 340B Steering Committee

## Program Oversight & Compliance

A hallmark of successful organizations is a strong oversight committee that takes a compliance first approach to managing the 340B Program across the organization.



### Roles & Responsibilities

- Maintain compliance foundation
- Implement internal controls
- Continuous internal monitoring
- Documented use of savings



### Diverse Stakeholders

- IT
- Legal
- Pharmacy
- Patient Services
- Compliance
- Finance

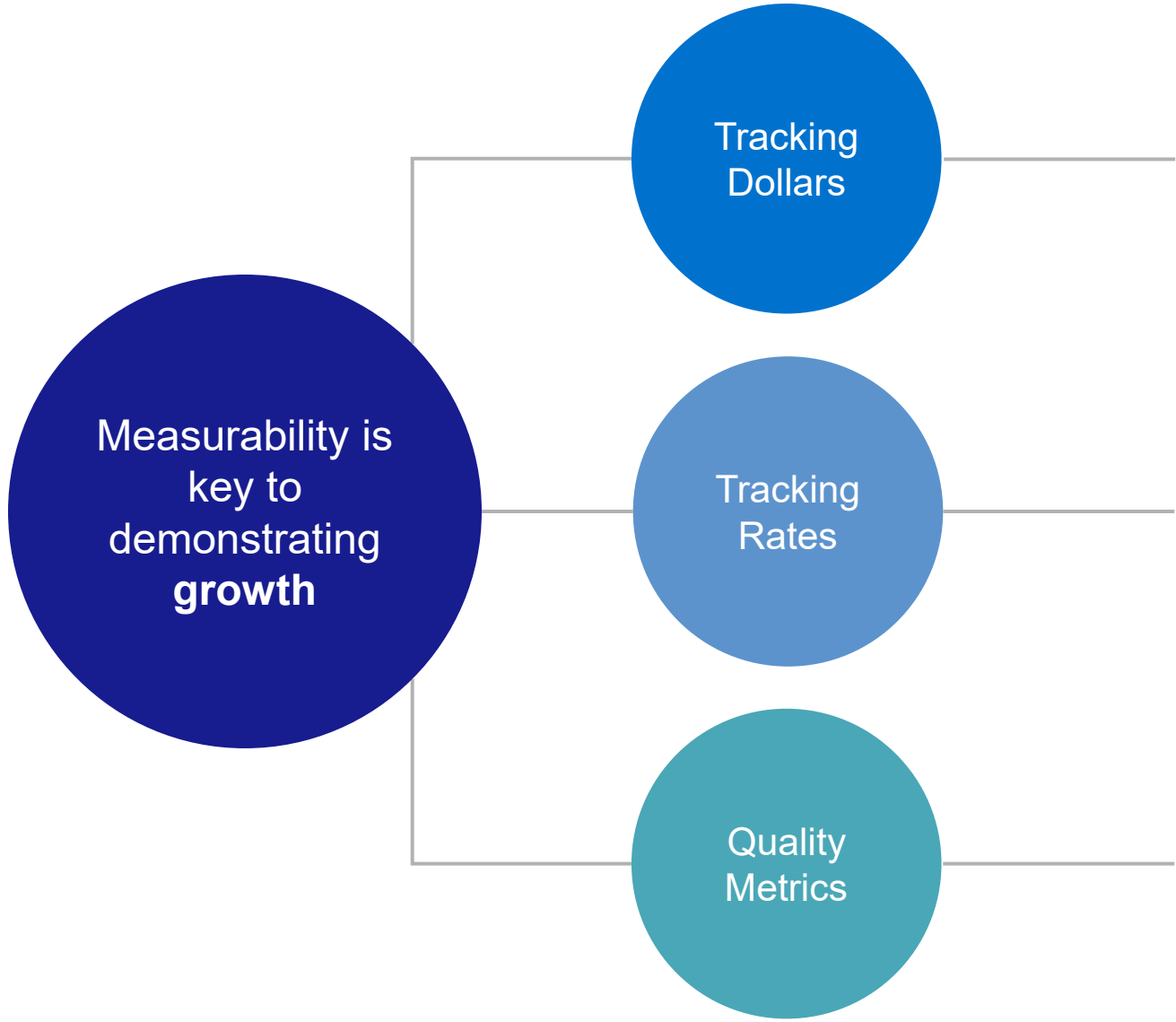


### Compliance

- Policies and procedures
- Conduct frequent mock audit procedures
- Utilize independent external reviews
- Medicaid BIN/PCN/GRPs
- Eligible locations
- Qualification parameters



# 340B KPIs



- 340B Revenue (Savings) and Reimbursement
- 340B Purchases
- Provider Productivity & the Value of Prescriptions
- Capture Rate
- Participation Rate
- 340B & non-340B Spend
- Maintenance Medication Adherence
- Percentage of Refills Filled
- Social Determinants of Health

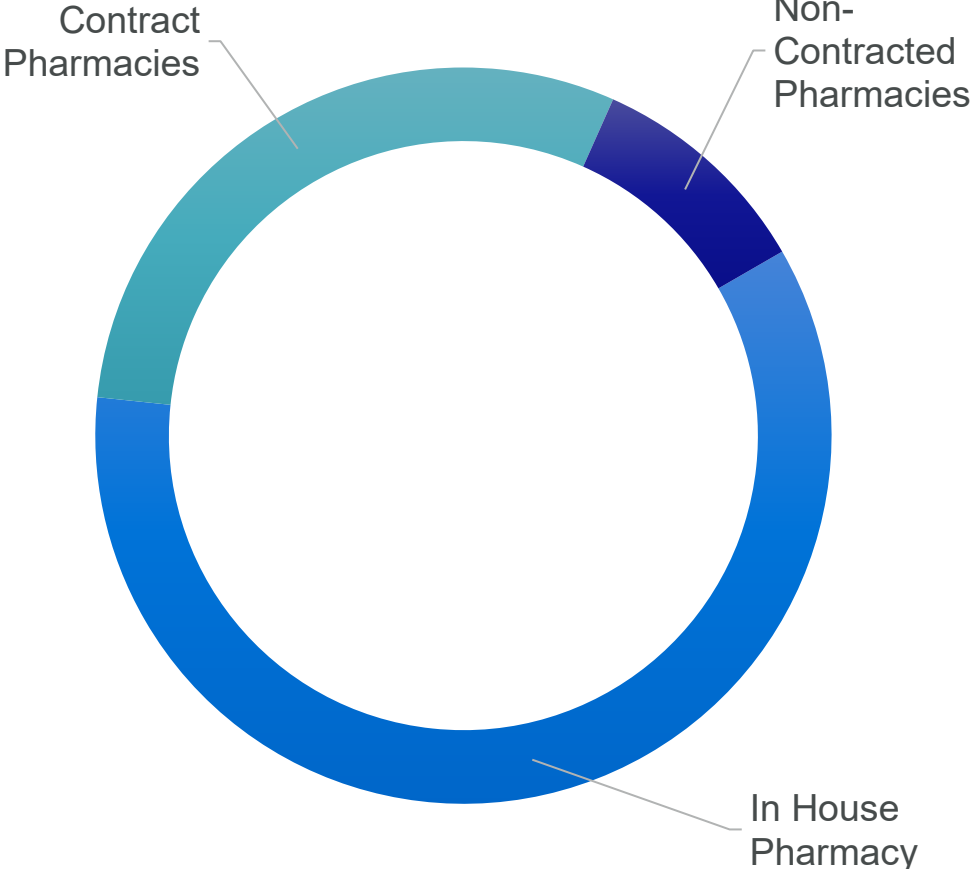
# Key Performance Indicator Capture Rate

Capture rate may be the most important performance indicator for your program and in-house pharmacies. Closely monitoring this metric is important to support patient care and access to medications.



Organizations should strive for a capture rate over

# 60%



# Key Performance Indicator

## 340B Savings

It is important for covered entities understand the impact the 340B Program has on communities and be able to communicate that impact.

1. Assess purchases across all 340B Program settings
2. Assess compliance costs including internal resources, vendors, and consultants
3. Assess the usage of 340B savings for the organization
4. Develop process to track and report the use of 340B savings

## Call to Advocacy

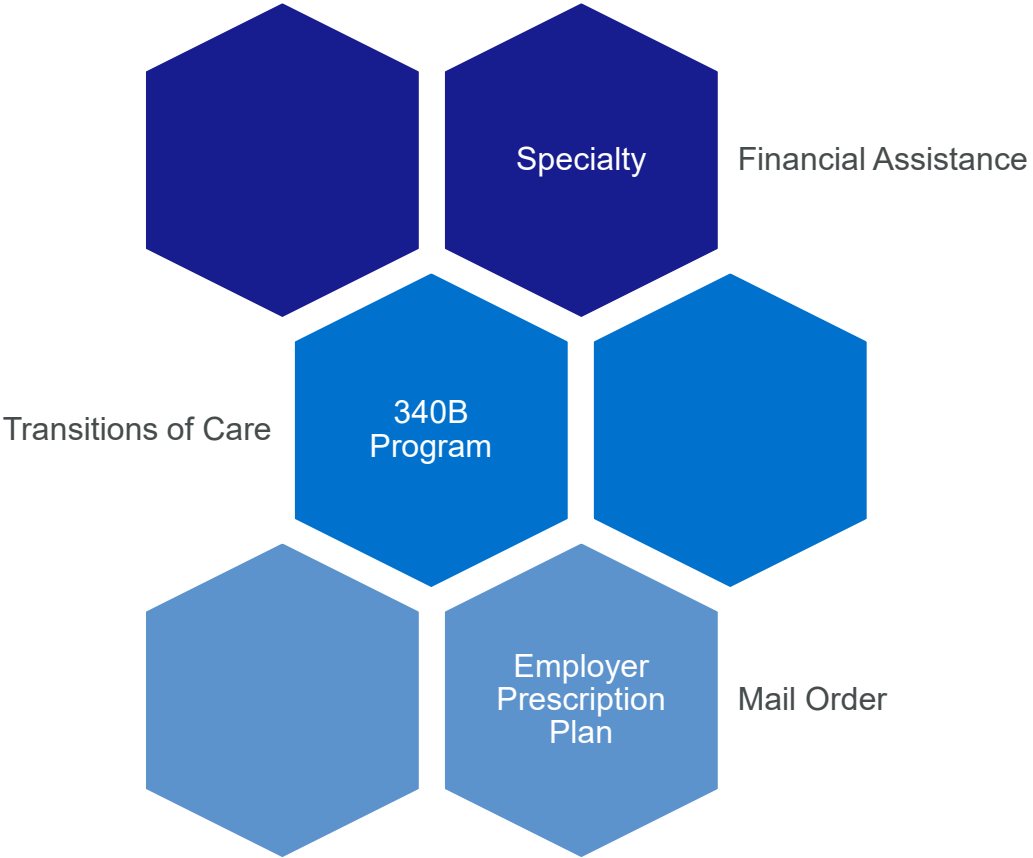
---

- Contact Congress and State Legislators
- Work with advocacy groups
- Report overcharges to HRSA
- Educate your board
- Maximize and maintain your 340B savings

# Community Pharmacy

## The Power of an In-House Pharmacy

In today's evolving healthcare landscape, the advantages of in-house pharmacies are becoming more important than ever.



### Why consider a pharmacy for your organization?

- High-quality patient care
- Access to medications
- Escalating administrative and dispensing fees
- Restrictive manufacturer policies for contract pharmacies
- Additional revenue stream



# Outpatient Pharmacy

## Expanding Ambulatory Pharmacist Roles

Integrating a clinical pharmacist into the care team with 340B knowledge is an often-overlooked component for covered entities looking to improve outcomes and place patients at the front of every decision.

### Components

- Services: pharmacotherapy, chronic care management (CCM), medication therapy management (MTM)
- Collaborative practice agreements
- Referral arrangements
- Documentation

### Considerations

- Comprehensive tracking mechanism
- Pharmacist as a qualifying provider
- Pharmacist embedded in a qualifying location
  - Medicare charges
  - Payor requirements / telehealth
- Meeting the patient definition
- Consistent billing practices for services across all payor types

### Risk Areas

- Patient definition
- Inadequate documentation
- Poor tracking / coordination of components
- Policies and procedures
- Differences in billing practices by payor
- Communication gaps between providers, patients, and pharmacists

# 03

## Manufacturer Barriers



# Contract Pharmacy Addressing Manufacturer Restrictions

Since September 2020, manufacturers have taken steps to unlawfully block and limit access to 340B savings. Hospitals lost \$1.1B in the 340B savings from only five manufacturers in 2021.

**75%**

of hospitals making cuts

**33%**

of hospitals at risk of closure

**39%**

average reduction in contract pharmacy benefit (CAH)

**23%**

average reduction in contract pharmacy benefit (DSH/RRC/SCH)



# Contract Pharmacy

## Addressing Manufacturer Policies



ESP  
Kalderos?  
Rebate model?



Direct  
Replenishment



Entity Owned  
Pharmacy

← Options available to covered entities to minimize impact of contract pharmacy restrictions →

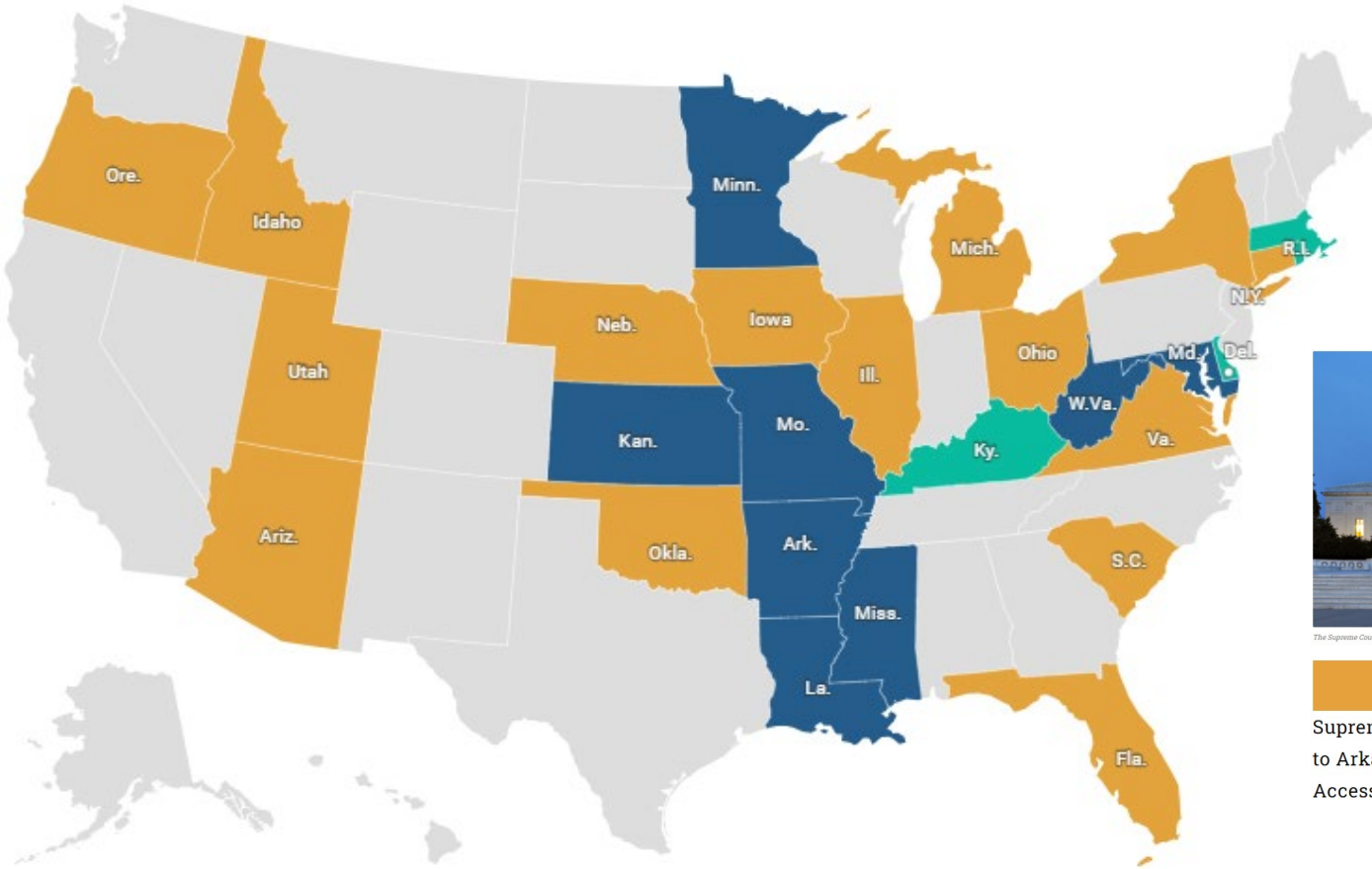


# Legislative Update

## Addressing Manufacturer Restrictions

### 340B REPORT Legislation Tracker: 2023-2024 State Bills and Laws that Prohibit Drugmaker 340B Contract Pharmacy Restrictions

- Bill passed
- Bill cleared a legislative chamber
- Bill introduced



The Supreme Court announced on Dec. 9 that it would not take up PHARMA's appeal challenging an Arkansas 340B law.

#### BREAKING NEWS

Supreme Court Declines to Hear PhRMA's Challenge to Arkansas' Landmark 340B Contract Pharmacy Access Law



# Rebate Model Litigation



Three manufacturers are suing to implement a rebate model.



## Wall Street Journal Reports Sanofi Will Become Third Drugmaker to Push for Controversial 340B Rebate

French pharmaceutical giant Sanofi reportedly plans to announce a 340B rebate model for hospitals today, making it the third drugmaker to attempt to unilaterally impose a 340B rebate system that providers and nearly 200 federal lawmakers argue would “devastate” the drug discount program.

Sanofi plans to notify hospitals on Friday that it will only offer 340B discounts through a post-purchase rebate upon collection of pharmacy and medical claims data beginning in early 2025, the Wall Street Journal [reported](#) late this morning. The planned announcement comes shortly after [Johnson & Johnson \(J&J\)](#) and [Eli Lilly](#) each sued the Health Resources and Services Administration (HRSA) to establish their own rebate models, which the agency maintains violate the 340B statute because they did not receive agency approval.

Sources:

1) <https://340breport.com/wall-street-journal-reports-sanofi-will-become-third-drugmaker-to-push-for-controversial-340b-rebate/>

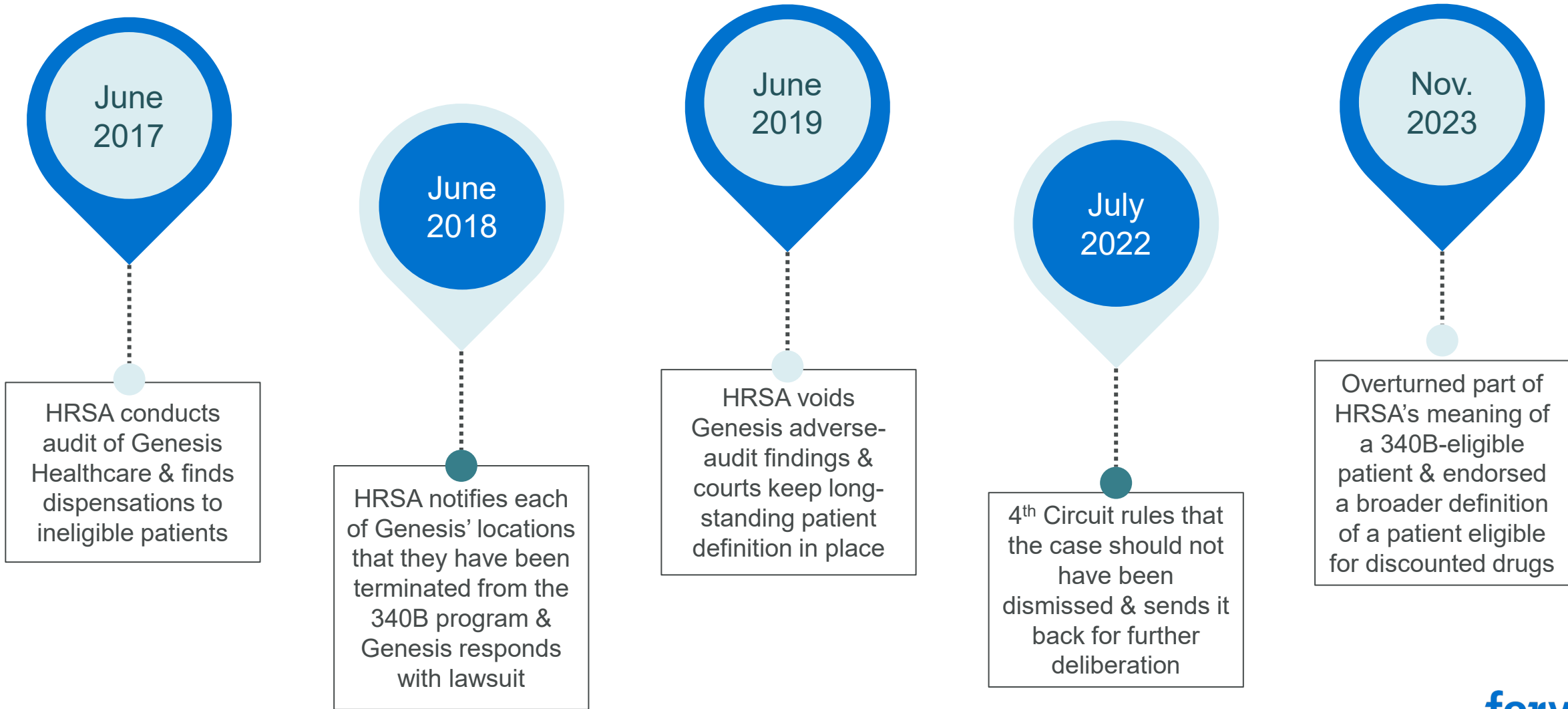
# 04

## 340B Program Outlook



# 340B Patient Definition

## Genesis Healthcare v. Becerra





# Legislative Update

## Changing Pricing Dynamics

Covered entities need to prepare for the proposed changes and implications of the Inflation Reduction Act (IRA).

### Drug Price Negotiation Program

- Drug Selections – only Part D drugs for 2026 & 2027
- Maximum Fair Price (MFP)
- Litigation

### Medicare Part B and Part D Inflation Rebates

- Manufacturers are required to pay a rebate on a unit of a drug paid under Part B or D where price of the drug increases faster than inflation.

### Medicare Part D Redesign

- Out of pocket threshold, coverage gap, insulin, vaccines

### Medicare Part B Reimbursement Changes

- Payment rate for biosimilars & add-on payments

## Important Dates

---

### January 1, 2024

- Removal of 100% AMP rebate cap

### January 1, 2026

- Drug negotiations take effect – 10 Part D drugs

### January 1, 2028

- Part B drugs to be included in negotiations

# Legislative Update

## Administrative Dispute Resolution (ADR)

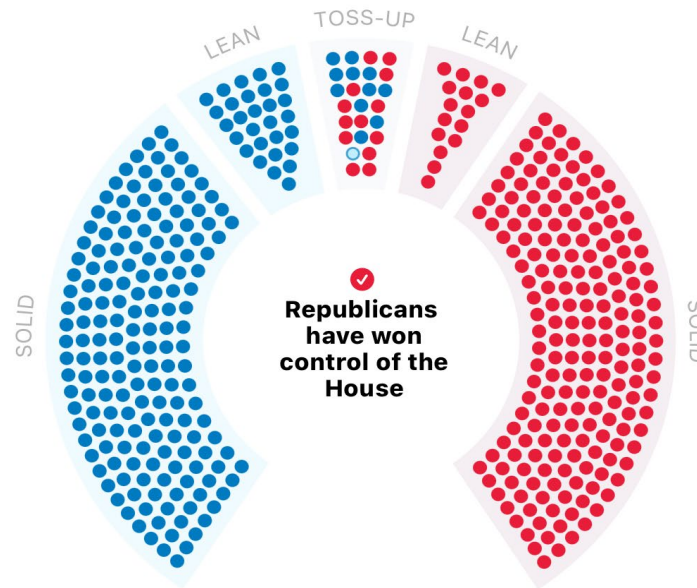
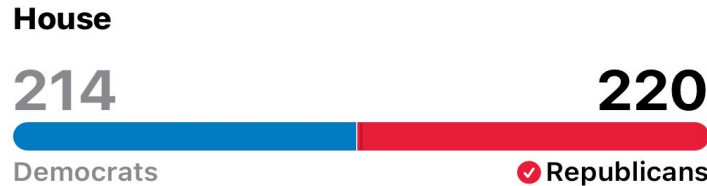


- 42 USC § 256b(d)(3) Administrative Dispute Resolution Process
- Rule created under the Affordable Care Act
  - Proposed rule not provided until 2016
- HHS issued final rule in 2020, though claims filed against rule leading to the new final rule being issued April 2024
- Final rule went into effect June 18, 2024
- Chevron implications

# 2024 Election – Congress

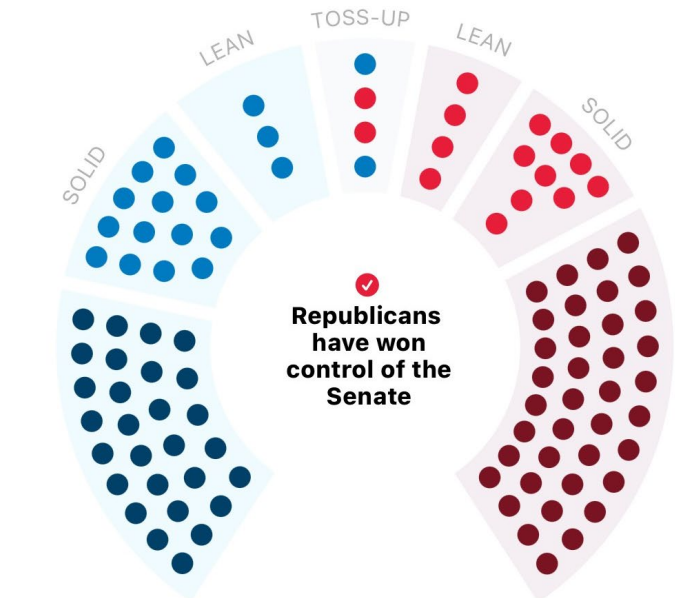
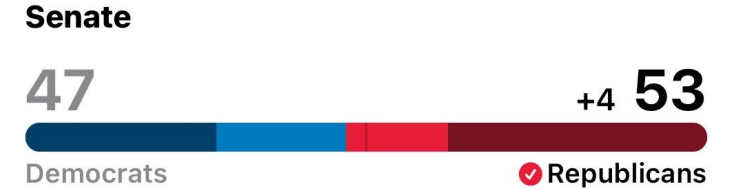


The Republicans have held the House of Representatives....  
...and have taken the Senate, enabling legislation to be passed by “reconciliation.”



Ratings: Cook Political Report

Lead      Called



Ratings: Cook Political Report

Lead      Called      Not up for election



# 2024 Election – Administration



Trump 47 will be more effective in the first 100 days than Trump 45.

How the regulatory environment changes will depend on appointments to HHS & CMS.

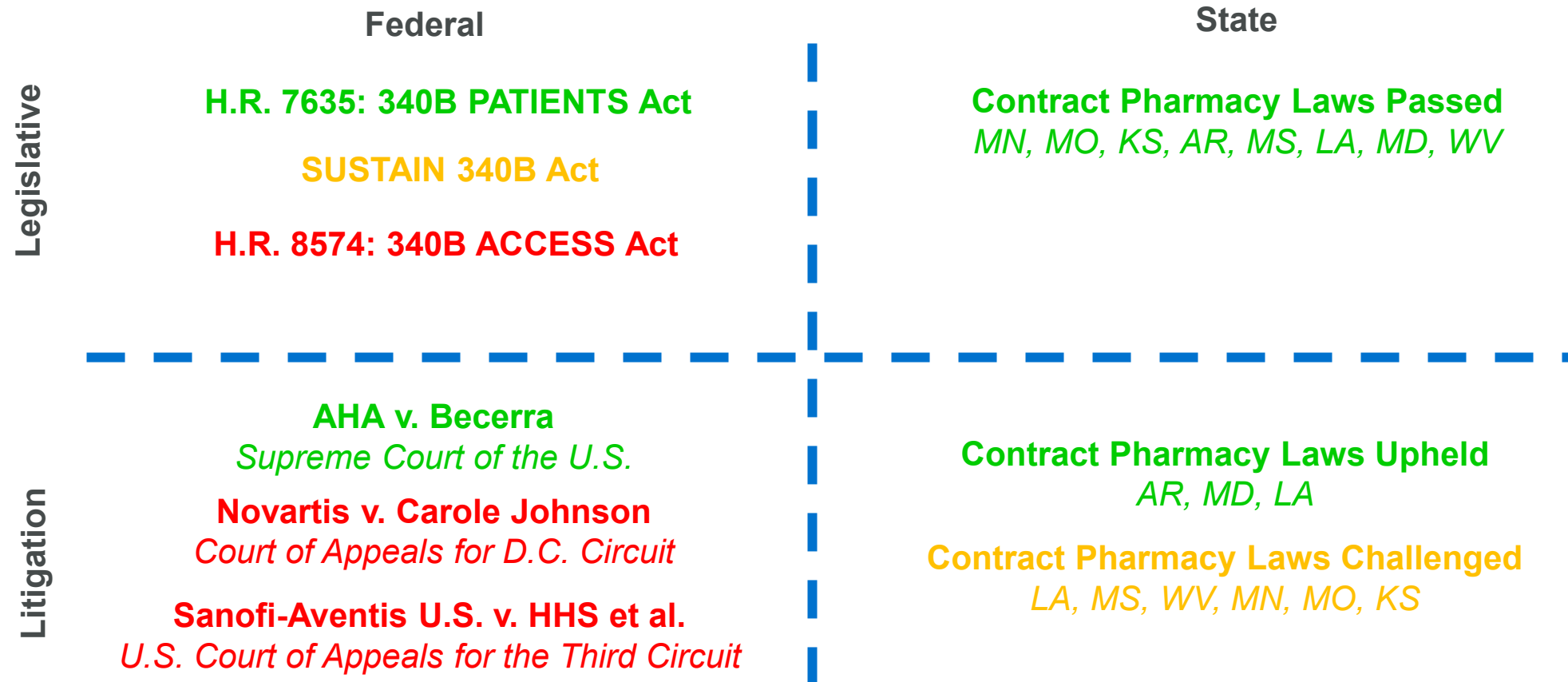




# 340B Legislation & Litigation

- Legislative action unlikely unless hospitals suffer a significant loss in court.
- The administration is likely to reduce Part B payments for 340B drugs...again.

## Federal & State 340B Activity

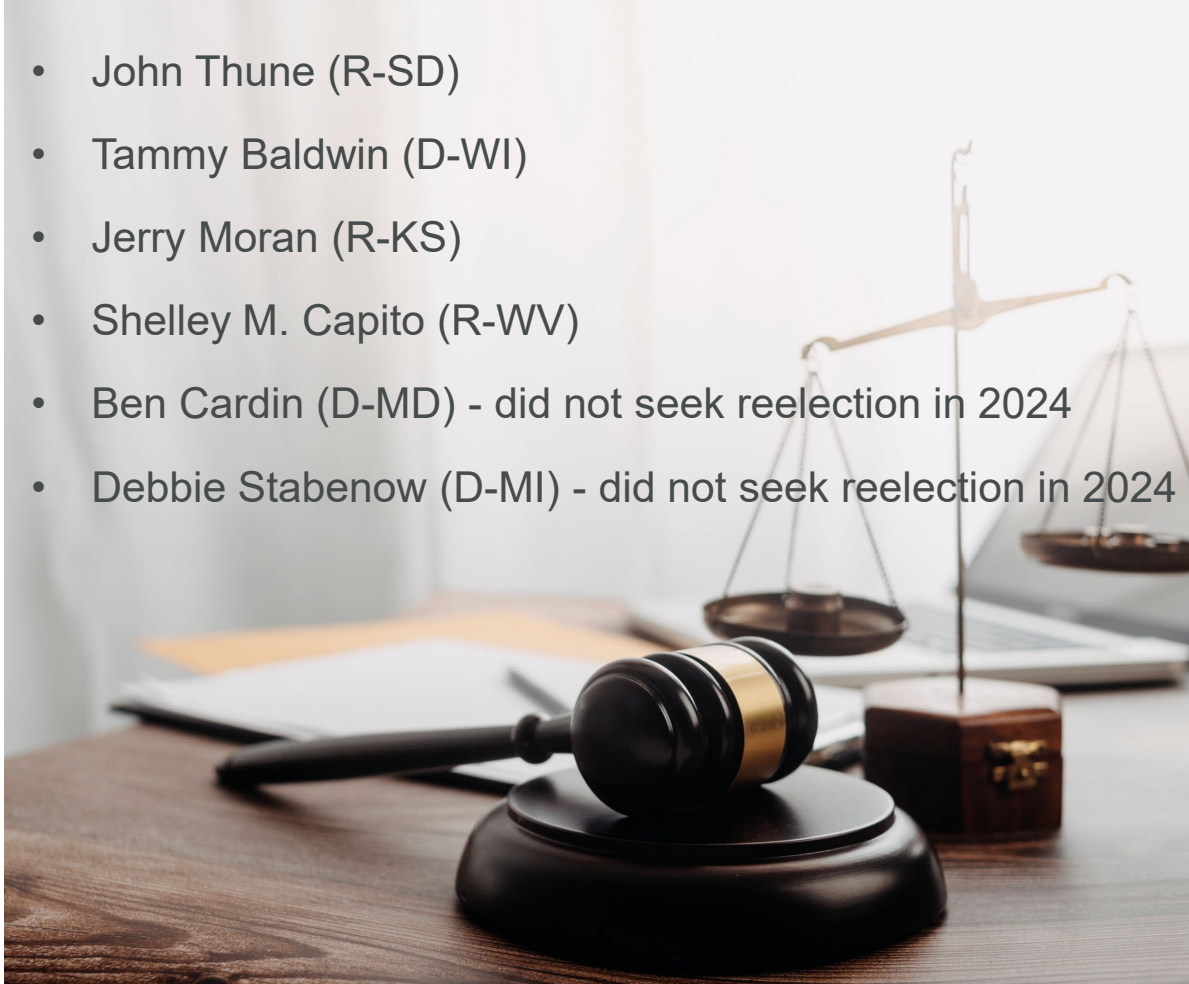


# Legislative Update

## **SUSTAIN 340B Act**

### Key Components

- 6 Bipartisan Senators (3 Republicans, 3 Democrats)
- Draft legislation after 6 months of meetings
- RFI – Due April 24, 2024
- Contract Pharmacy
- Transparency
- Program Integrity
- Duplicate Discounts
- PBM/Insurer Provisions
- Additional Provisions

- 
- John Thune (R-SD)
  - Tammy Baldwin (D-WI)
  - Jerry Moran (R-KS)
  - Shelley M. Capito (R-WV)
  - Ben Cardin (D-MD) - did not seek reelection in 2024
  - Debbie Stabenow (D-MI) - did not seek reelection in 2024



# Issues to Watch



Over the next two years there are many health policy issues likely in play that could impact organizations' finances.

## Select Health Policy Issues In Play

Medicaid	Exchange Subsidies & Insurance Market "Reform"	Medicare Advantage
Site-Neutral Payments	<b>340B</b>	Price Transparency
SNF Staffing Ratios	Transition to Value	Tariffs/ Supply Chain

Additional Details Available At:

[www.forvismazars.us/forsights/2024/11/2024-election-implications-healthcare-organizations-health-policy](http://www.forvismazars.us/forsights/2024/11/2024-election-implications-healthcare-organizations-health-policy)

# Legislative Update

## Visits with Congress

- 15 Congressional offices
- Advocacy organizations
- “Good” & “bad” players
- Will need compromise between all 340B parties
- Watching for future rule changes



# Advocacy Action Steps



Contact Congress & state legislators



Work with advocacy groups



Report overcharges to HRSA



Educate your board



Maximize & maintain your 340B savings

**Questions?**



# Contact

## Forvis Mazars

### Brian Bell

Principal

P: 513.562.5562

[brian.bell@us.forvismazars.com](mailto:brian.bell@us.forvismazars.com)

The information set forth in this presentation contains the analysis and conclusions of the author(s) based upon his/her/their research and analysis of industry information and legal authorities. Such analysis and conclusions should not be deemed opinions or conclusions by Forvis Mazars or the author(s) as to any individual situation as situations are fact-specific. The reader should perform their own analysis and form their own conclusions regarding any specific situation. Further, the author(s)' conclusions may be revised without notice with or without changes in industry information and legal authorities.

© 2024 Forvis Mazars, LLP. All rights reserved.