



Navigating the 340B Drug Pricing Program Key Updates and Strategies

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Navigating the 340B Drug Pricing Program

Meet the Presenter



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Navigating the 340B Drug Pricing Program

Learning Objectives

- Understand the history, purpose, and key components of the 340B Program
- Understand the importance of internal oversight and controls in managing the 340B Program.
- Explore methods for tracking and analyzing the profitability of the 340B Program.
- Learn how to optimize savings and maximize the benefits of the program for hospitals
- Identify tools and resources available to hospitals for tracking and maximizing 340B savings
- Understand the role of contract pharmacy networks in the 340B Program.
- Explore methods for optimizing program performance and achieving organizational goals
- Understand the current landscape of the 340B Program and the challenges it faces.
- Explore the potential future direction of the 340B Program.





Forvis Mazars

Overview

With a legacy spanning more than 100 years, Forvis Mazars is committed to providing a different perspective and an unmatched client experience that feels right, personal and natural. We respect and reflect the range of perspectives, knowledge and local understanding of our people and clients. We take the time to listen to deliver consistent audit and assurance, tax, advisory and consulting services worldwide.

We nurture a deep understanding of our clients' industries, delivering greater insight, deeper specialization and tailored solutions through people who listen to understand, are responsive and consult with purpose to deliver value.

Deep industry understanding

Forvis Mazars' deep understanding of industry-specific environments, issues and trends helps us anticipate and address evolving needs to prepare you for strategic opportunities ahead.

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We serve global industries including:

- Financial Services
- Manufacturing & Distribution
- Technology, Media & Telecommunications
- Life Sciences
- Private Equity

\$5B

combined revenue
(2023)

100+

combined countries,
territories & markets

400+

combined offices
& locations

1,800+

combined partners

40,000+

combined team members

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**forvis
mazars**

U.S. Presence

Top 10

U.S. Public Accounting Firm

\$2bn

Revenue (2023)

79

Markets

28

States

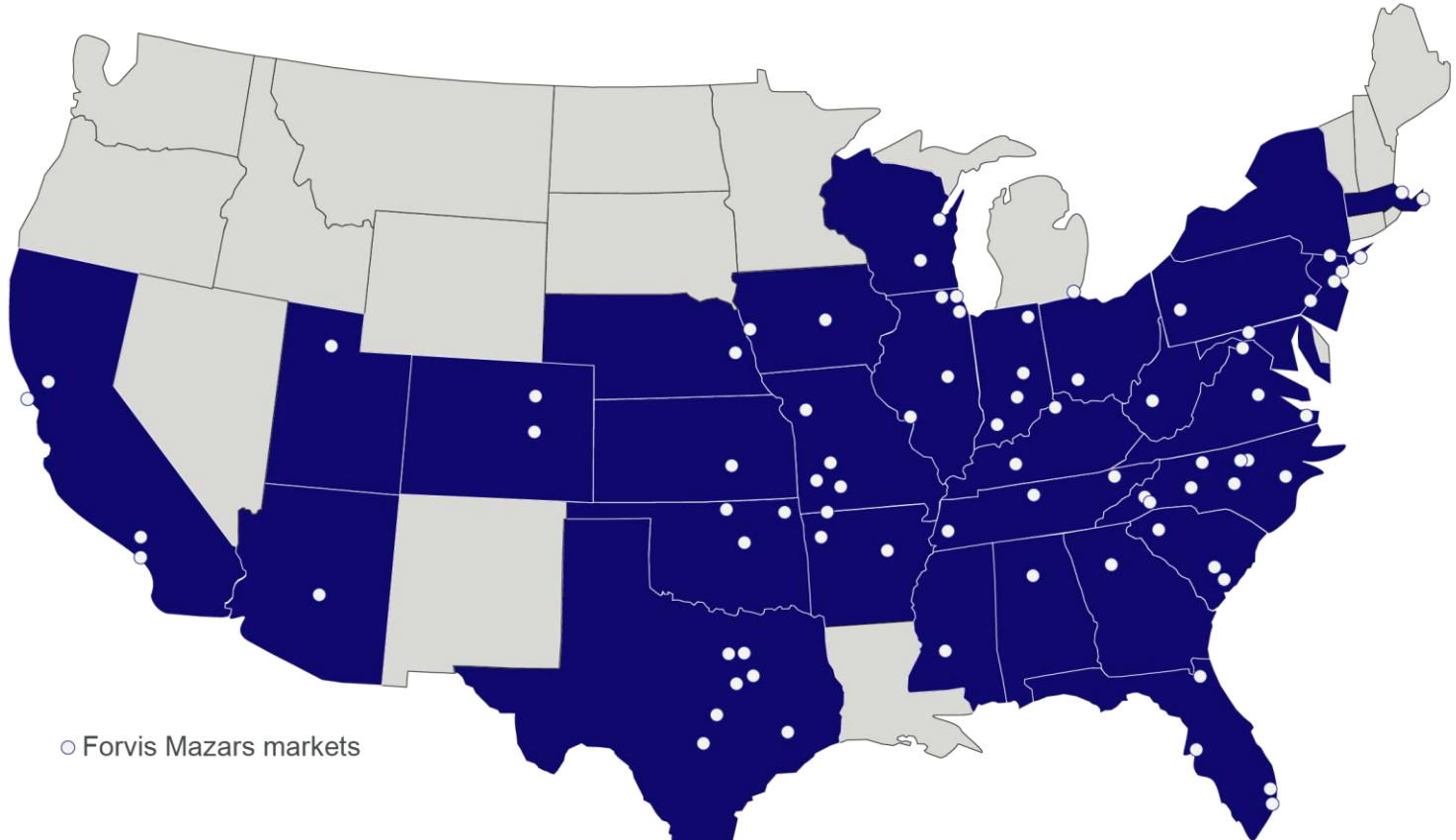
600+

Partners & Principals

7,000+

Employees

Source: Inside Public Accounting, based on most recent rankings
2023 combined revenues: FORVIS \$1.7bn, Mazars USA (expected) \$305M

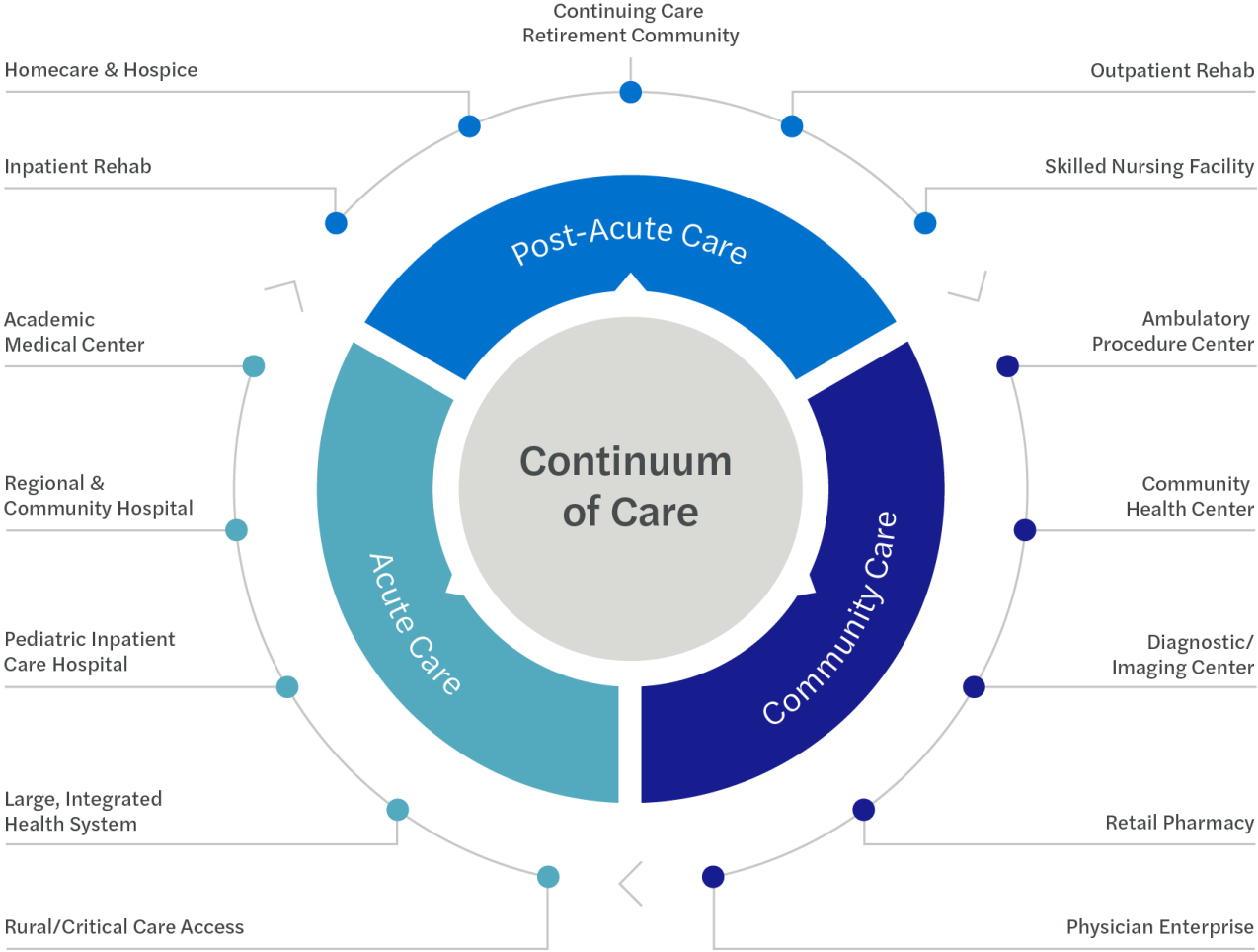


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- Forward-looking academic medical centers that care for our sickest patients while training the next generation of providers.
- Community health centers that strive to improve the health of the populations they serve through quality care that is close to home.
- Ambulatory and post-acute providers that extend beyond the four walls of the hospital to bring care out of the costliest setting.

We have hundreds of dedicated healthcare consultants who understand the challenges today's environment presents.



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Leveraging Our Forward Vision to Help You Achieve Financial & Operational Excellence

Forvis Mazars has designed its healthcare consulting solutions portfolio specifically to address a healthcare organization's unique and complex challenges and opportunities. We combine informative analytics and deep technical resources and competencies to help you make informed decisions that drive value, quality, and results.



Strategy & Finance

Mergers, Acquisitions & Partnerships, Organizational Health, Physician Alignment, Strategic Planning, Value-Based Care, Dynamic Financial Modeling, Financial System Optimization, Prospective Reporting & Feasibility Studies, and Payor Strategies



Healthcare Reimbursement

Cost Reporting, DSH & Uncompensated Care Reporting, Medicare Bad Debt, Regulatory Compliance, Post-Acute Care Targeted Offerings, and Strategic Reimbursement Offerings



Performance Improvement

Clinical Documentation: Integrity, Improvement & Coding, Clinical & Operational Excellence, Cost Management, Pharmacy & 340B, Physician Services, and Revenue Cycle & Integrity



Payor Services

Growth & Strategy, Mergers & Acquisitions, Risk-Based Contracting & Reporting, Compliance, Accreditation & Credentialing, Survey Services, Risk Mitigation, Transformation, Business Intelligence, and Managed IT Services

9th

Largest Healthcare Consulting Firm (2023)

92

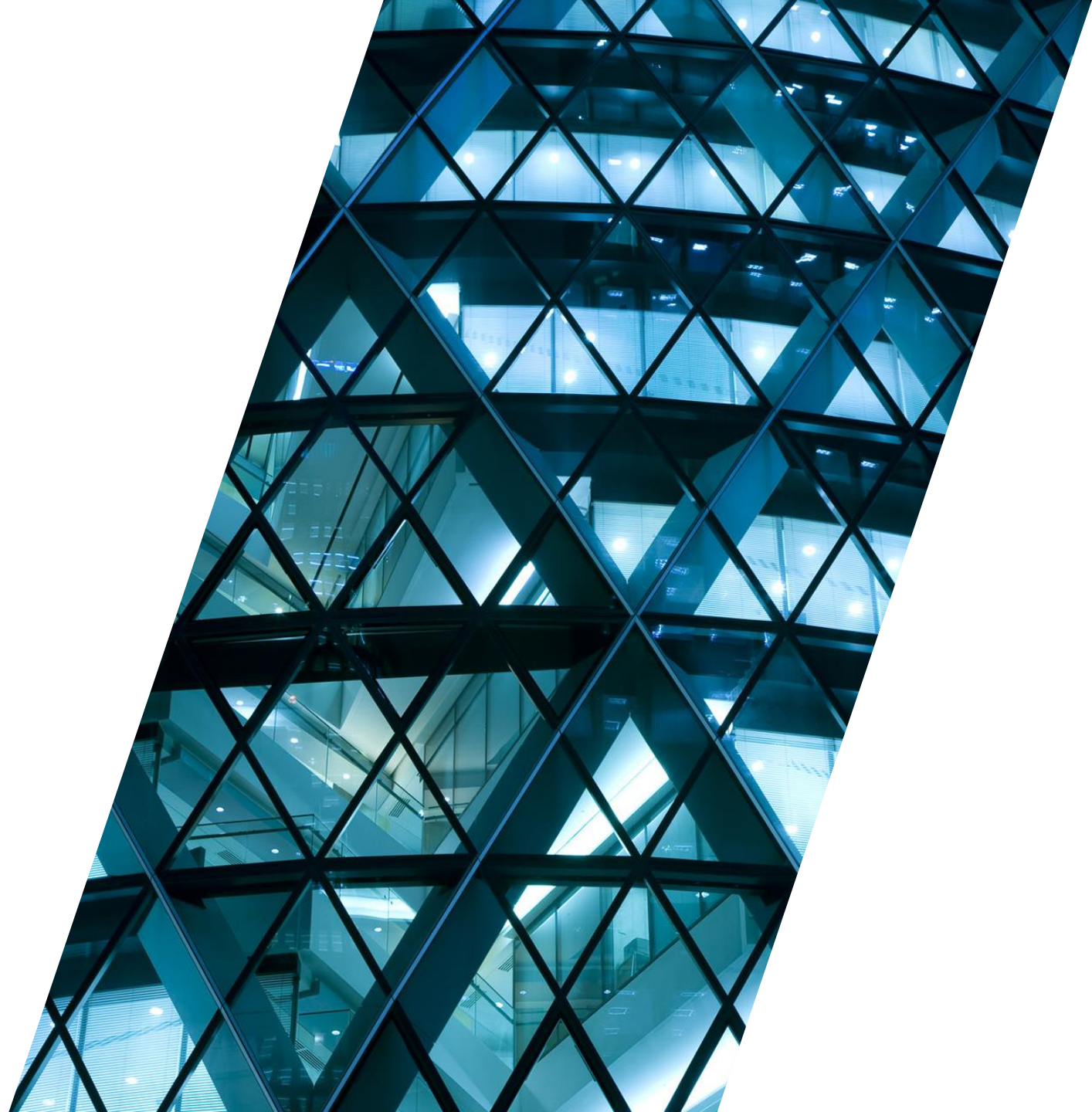
Net Promoter Score®

Modern Healthcare's Largest Management Consulting Firms 2023 ranking and UCX survey NPS®

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07

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

340B Program Eligibility

Understanding Participation

	PED	DSH	CAN	CAH	RRC	SCH
Subject to GPO Prohibition	X	X	X			
Subject to Orphan Drug Exclusion			X	X	X	X
Disproportionate Share Adjustment %	>11.75	>11.75	>11.75		≥8.0	≥8.0
Designated by CMS	X			X	X	X

HRSA Audits

Results are made publicly available	Initially had an educational tone, but have since turned punitive with the introduction of penalties for non-compliance
Conducted by the Bizzell Group	
Focus on contract pharmacy arrangements, diversion, duplicate discounts, & database records	

YTD FY23 Statistics

- Results posted for 152 audits (as of July 24, 2024)
- 65 audits resulting in Corrective Action Plans
- 35 audits resulting in manufacturer repayment
- Audits occurred in 39 states

Manufacturer Audits

May only conduct
after showing
“reasonable
cause”

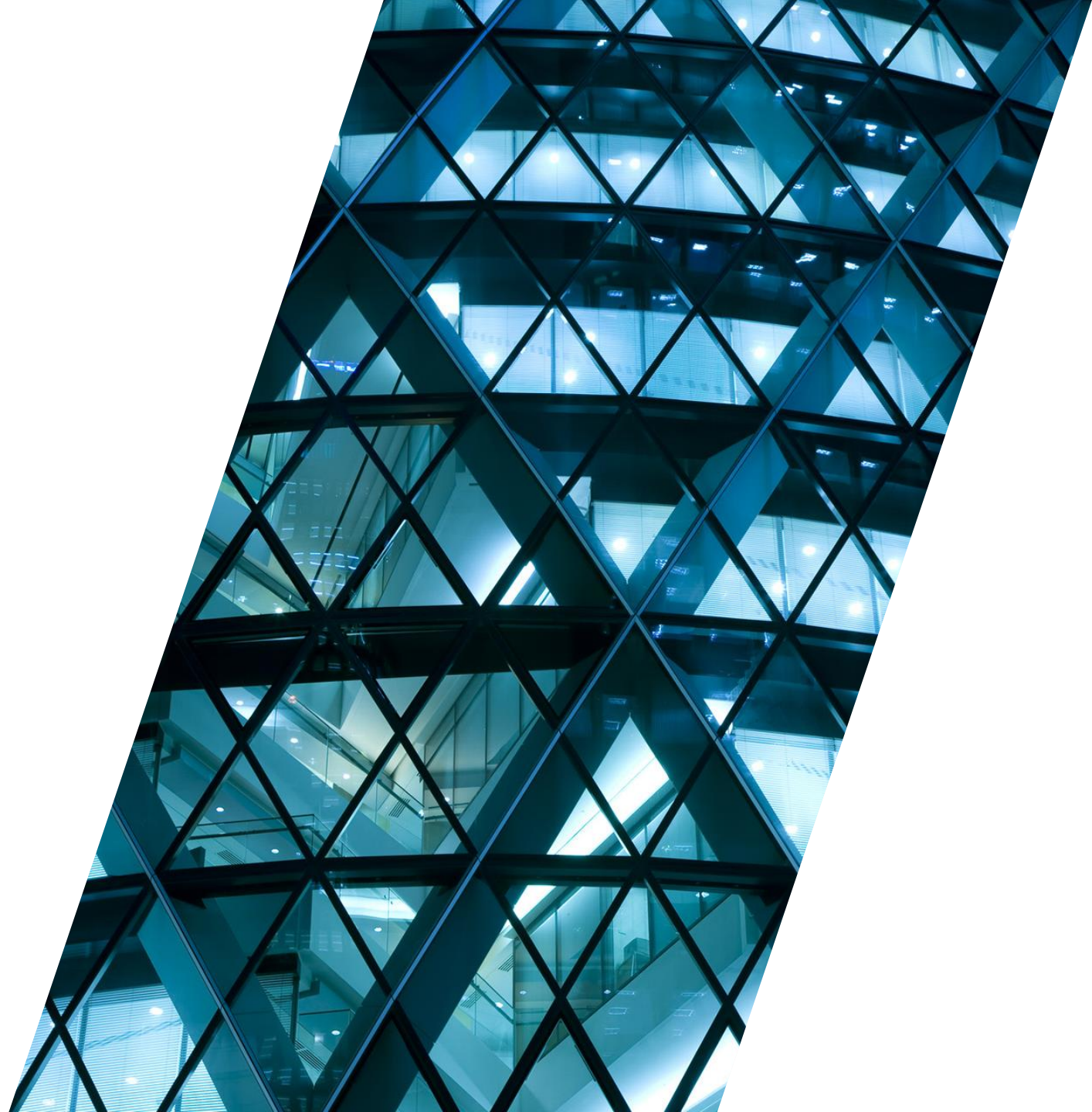
Manufacturer
inquiries to
covered
entities may
help support
“reasonable
cause”

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

Details are not
publicly available

12

340B Program Strategy



340B Steering Committee

Program Oversight and 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

Provider-Based Billing Clinics Path to the 340B Program



Financial

- 340B Impact
- Reimbursement impact from affected payors
 - Co-insurance impact on patients
- Any applicable costs associated with getting clinics to standard



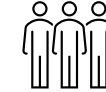
Accreditation

- Clinics must be up to hospital standards
 - Specifics depend on accrediting body
 - Potential site-visits
- Appropriate licensure



Integration

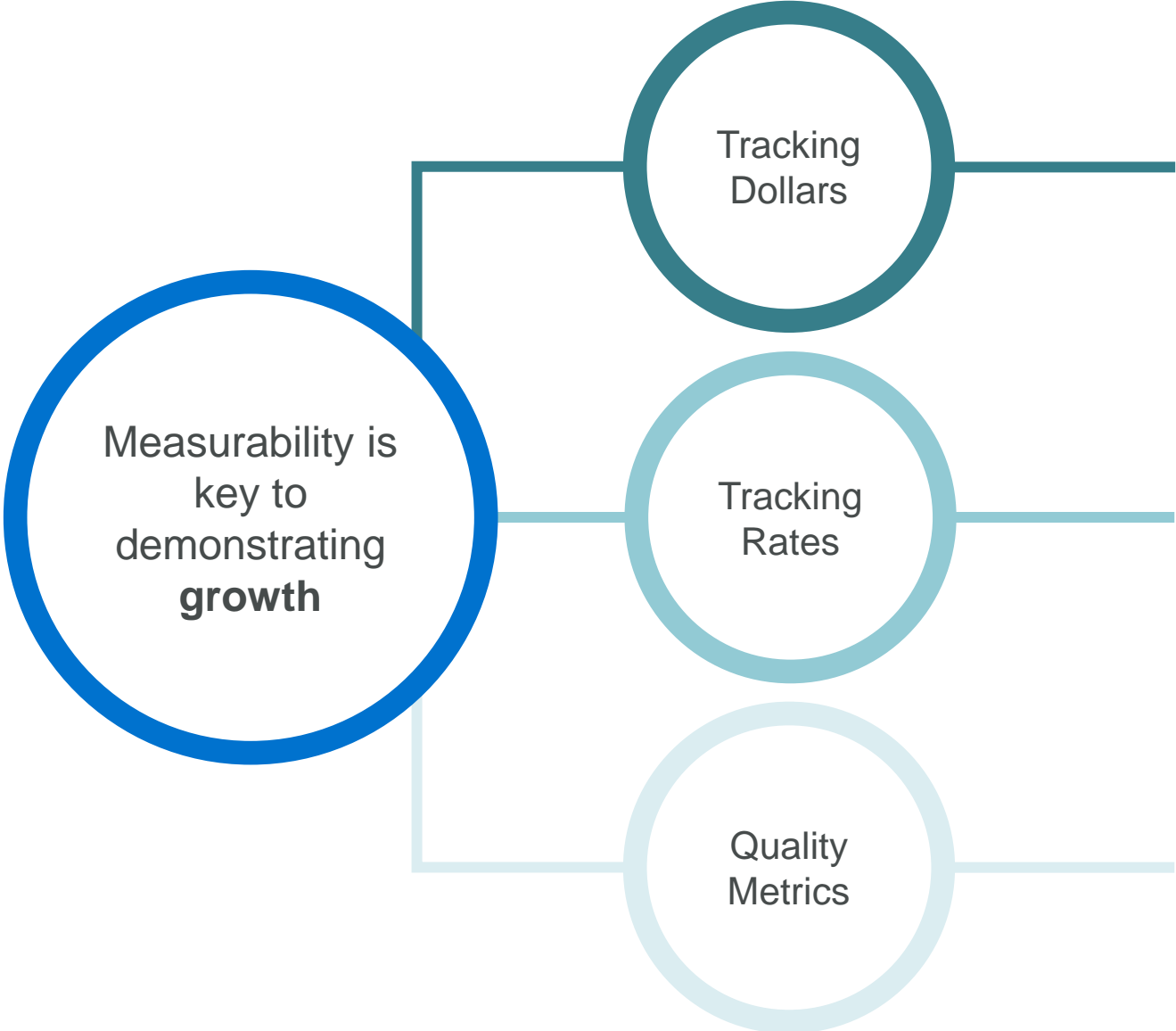
- Clinical integration
 - Clinical staff
 - Reporting structures
- EHR integration
- Financial integration
- Included on most recently filed Medicare Cost Report
- OPAIS registration
- Policies & procedures



Public Awareness

- Clinics must have naming associated with hospital
- Will need to update all collateral & signage
- Patient and staff education

340B KPIs

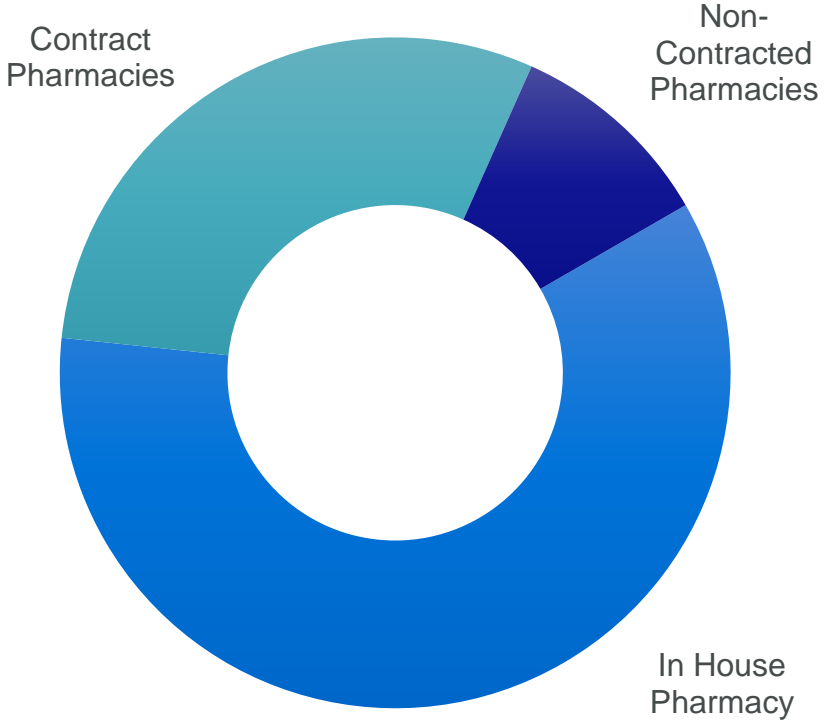


- 340B Revenue (Savings) and Reimbursement
- 340B Purchases
- Provider Productivity & the Value of Prescriptions
- Capture Rate
- Participation Rate
- 340B and non-340B Spend
- Maintenance Medication Adherence
- Percentage of Refills Filled
- Social Determinants of Health

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

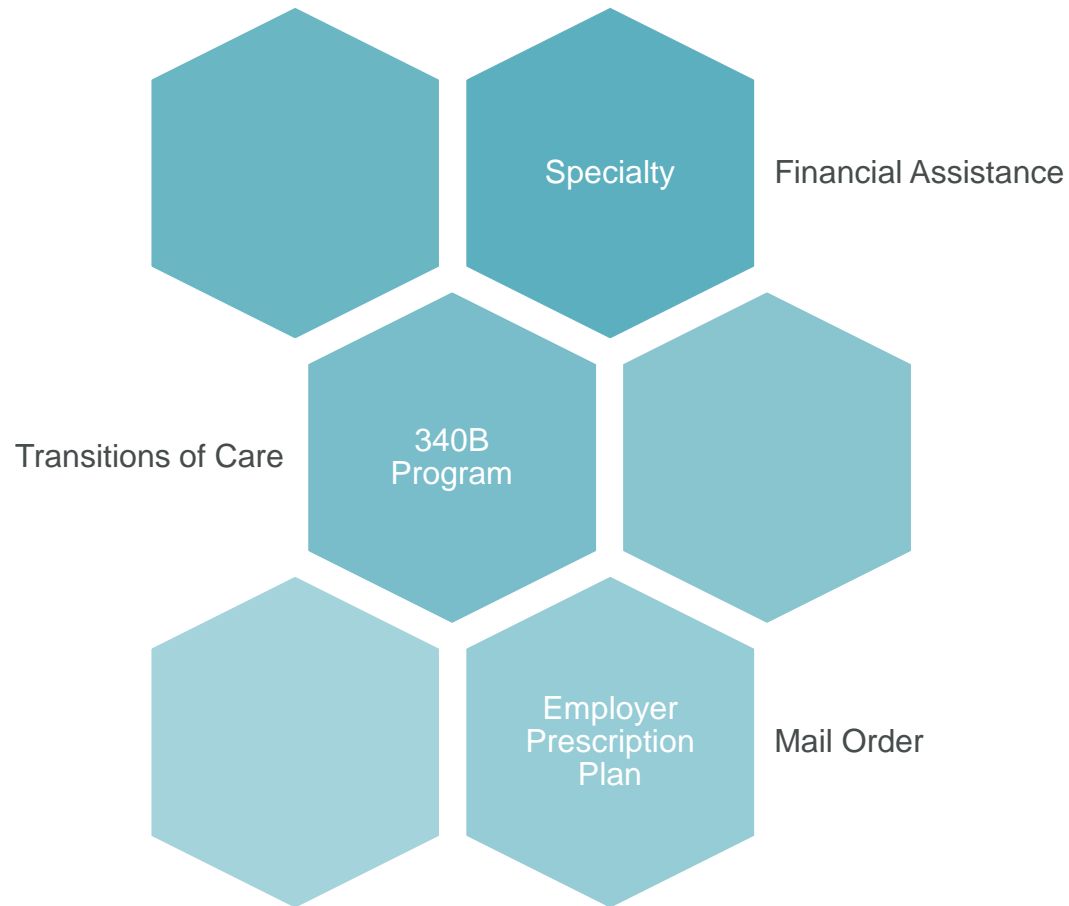
Call to Advocacy

- 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

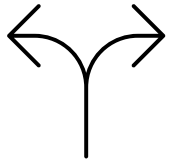
Considerations

- 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

340B Operations Vendor Management

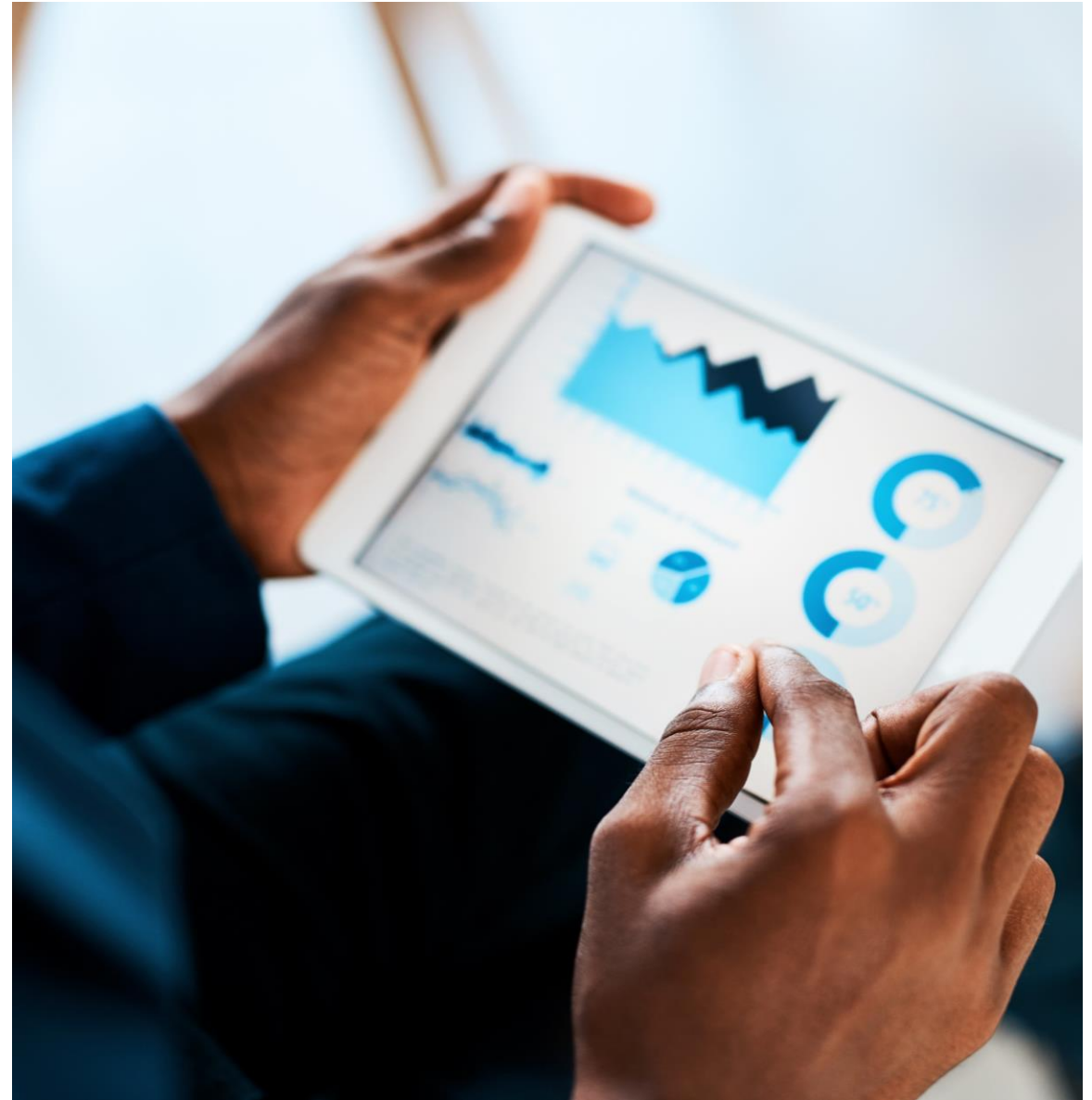


Split Billing Software

- Data feed review
- Accumulator & utilization review
- Routine monitoring practices

Third Party Administrators (TPAs)

- Review data feeds
- Review settings: qualification, locations, providers, exclusions, etc.
- Contract alignment & performance



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.



Source: 340B Health

- 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 Restrictions

Goal:
Improve 340B
transparency



- Owned by Second Sight Solutions
- Purported to help the prevention of duplicate discounts
- Claims data is requested for all payers
- Works best if protections exist against discriminatory reimbursement practices
- “The manufacturer’s view of duplicate discounts is different than that of a CE ...”

Contract Pharmacy

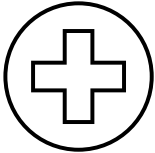
Addressing Manufacturer Policies



ESP



Direct Replenishment

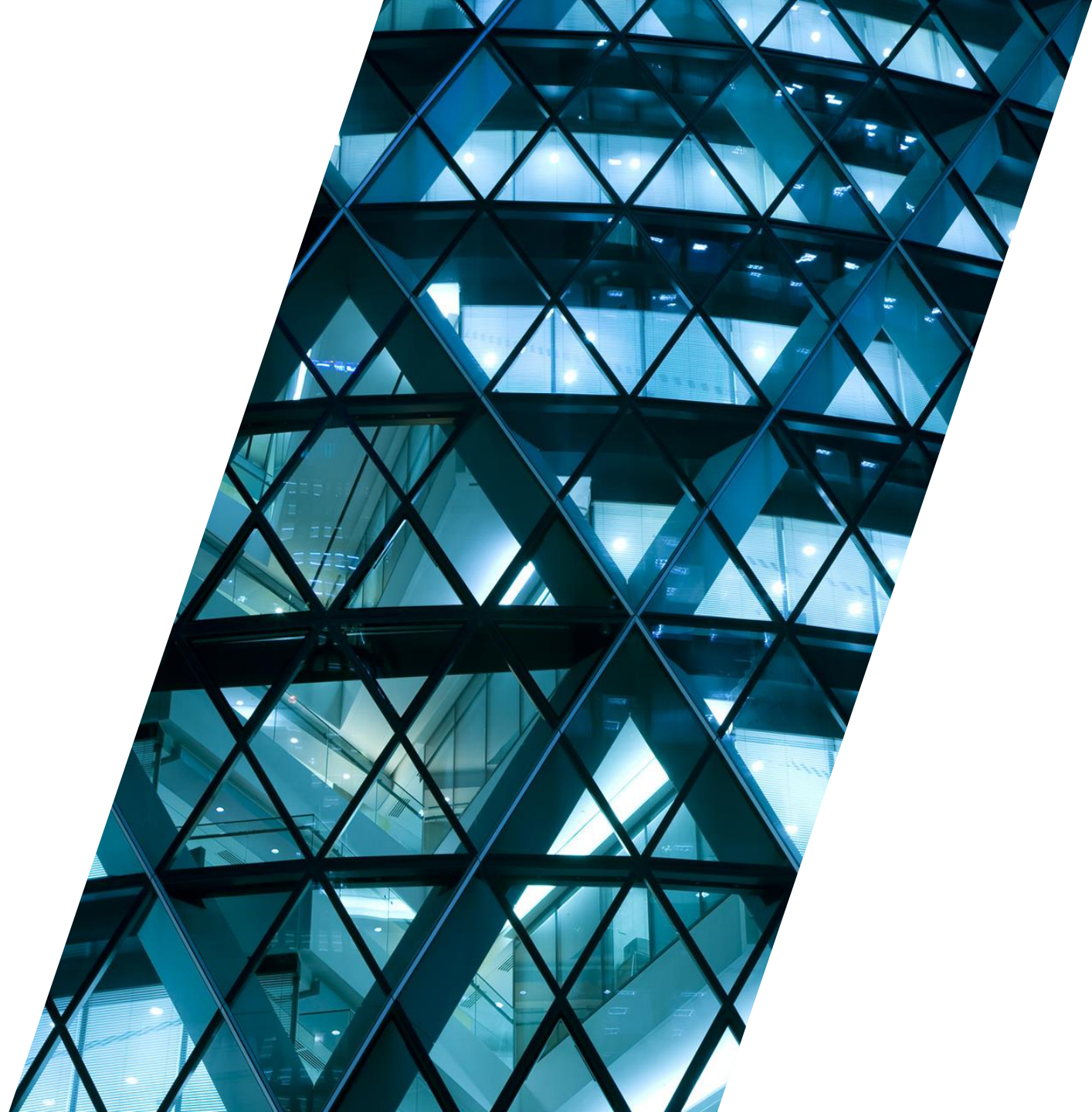


Entity Owned Pharmacy

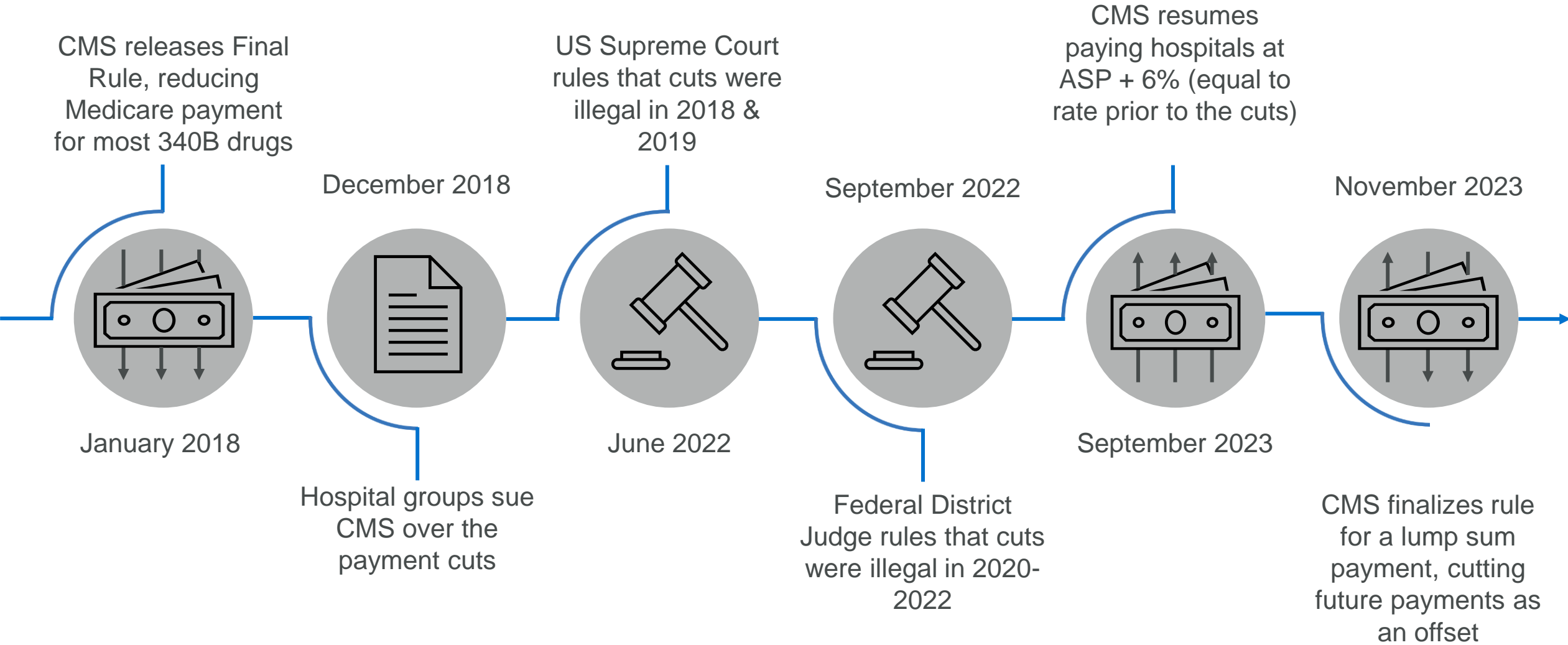


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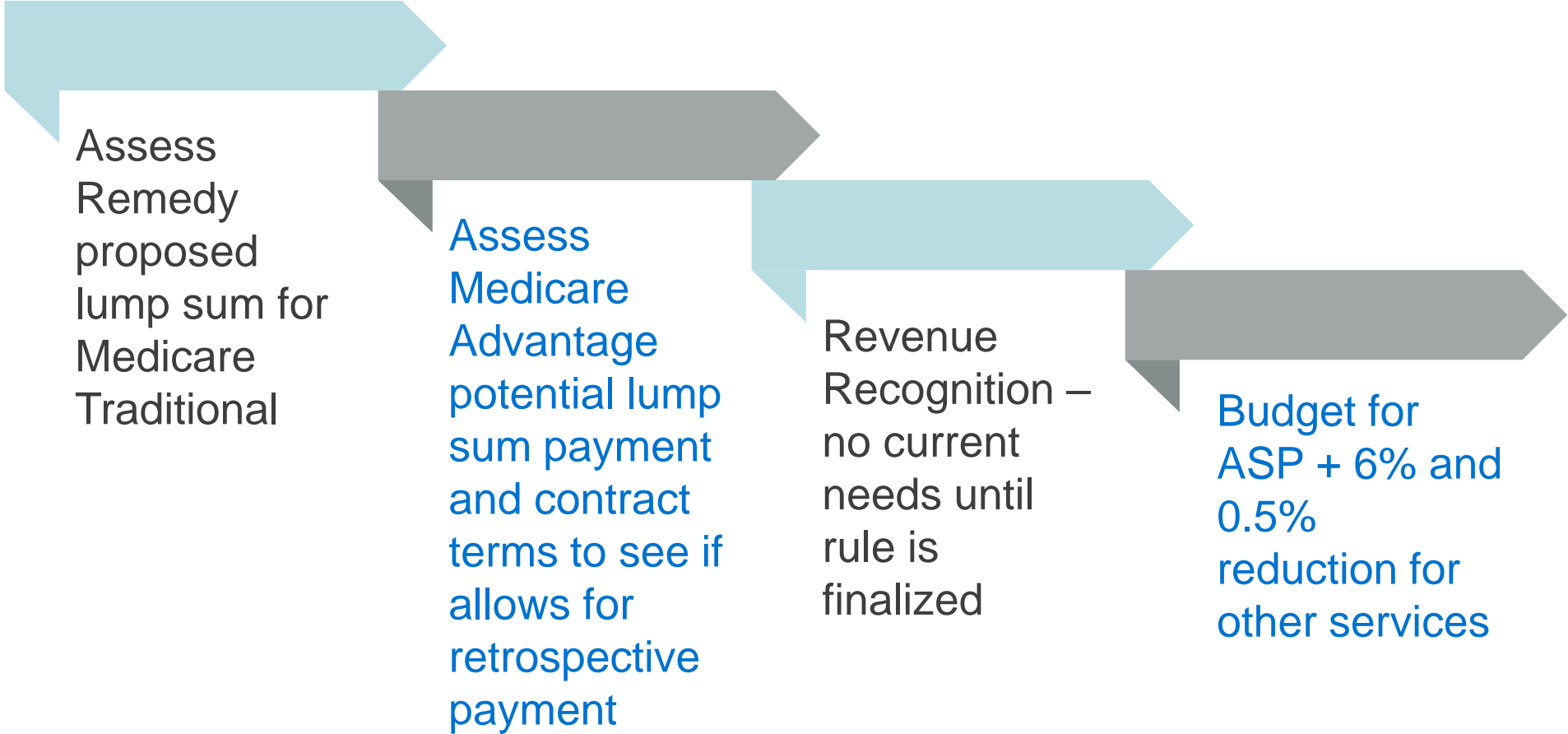
340B Program Outlook & Updates



OPPS Remedy Timeline

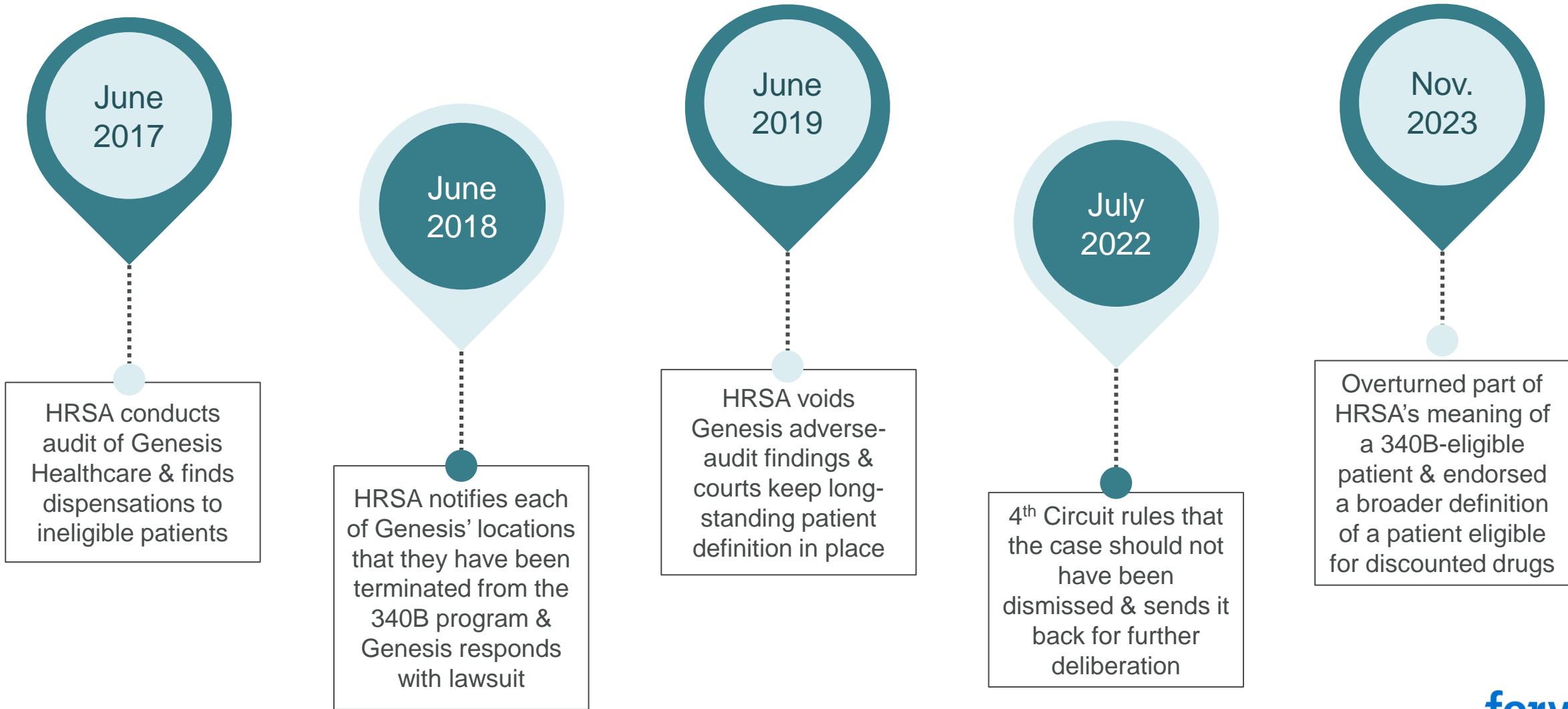


OPPS Remedy – Action Steps

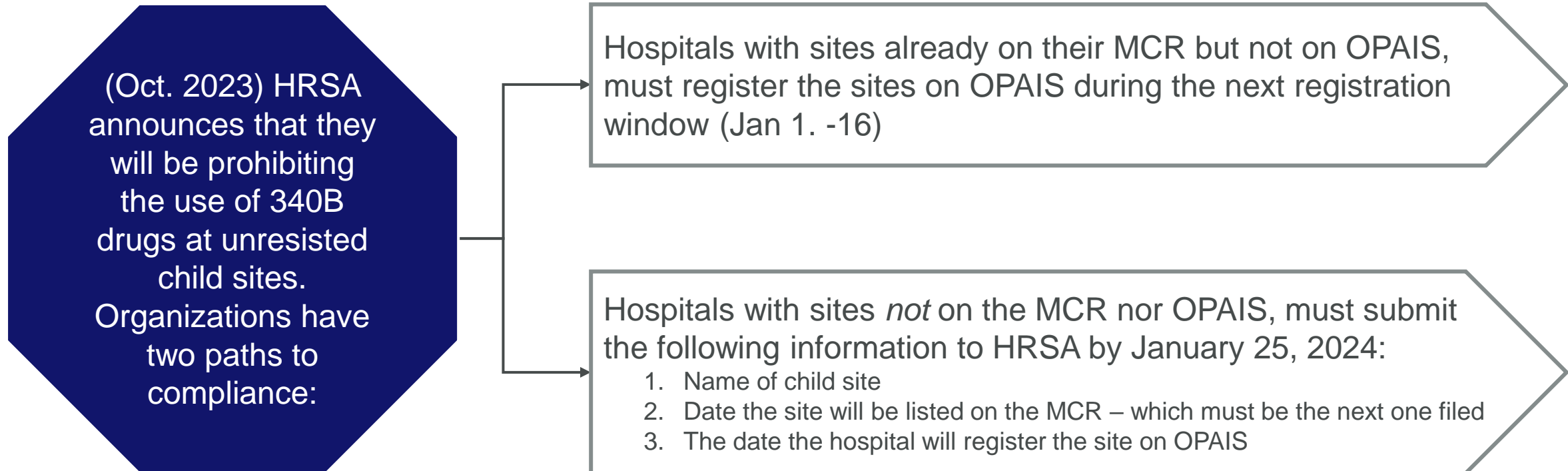


340B Patient Definition

Genesis Healthcare v. Becerra



Unregistered Child Sites Path to 340B Program Participation

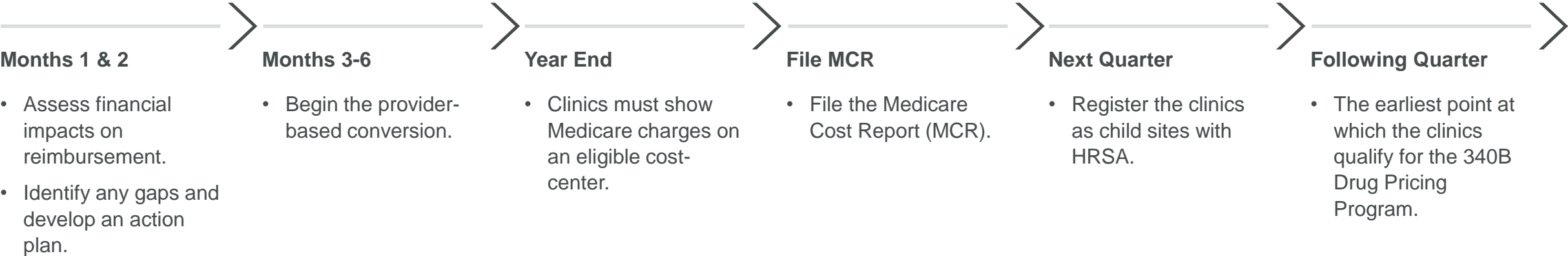


A lawsuit of more than 40 hospitals and health systems is currently being pursued against HRSA as it relates to this ruling.

Outline

Provider-Based & 340B Timeline

The following timeline outlines converting non-eligible departments and completing child site registration for the 340B Drug Pricing Program. Process may take **18-24** months.



Who Needs to be Involved?

Key Departments for Success: Leadership, Revenue Cycle, Finance, HR, Marketing, Compliance, Legal, Facilities, Patient Care

Inflation Reduction Act

Overview

Key Components

- 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

Inflation Reduction Act 340B Program

Covered entities need to prepare for the proposed changes and implications of the IRA. It is important to be actively assessing the impact to program performance in anticipation of changes.

- Removal of 100% AMP rebate cap
 - Slow rate of price increases
 - Lower prices
 - Medicaid best price
 - 340B ceiling price
 - Penny pricing
- MFP implications
 - Difference between MFP and 340B price
 - MFP below 340B price
 - Contract pharmacies
- CMS Guidance December 2023
- CMS 2025 physician fee schedule proposed rule



Assess operational changes & financial impacts to program

Inflation Reduction Act

Modifiers for Covered Entities

- The Part B Inflation Rebate does not include drugs already purchased at a discount through the 340B program
 - Modifiers help CMS identify drugs purchased with a 340B discount so as to effectively exclude them from the Part B inflation rebates
 - Beginning January 1, 2024, every entity will be required to use billing modifiers on separately payable claim lines for drugs purchased at 340B prices
 - CMS issued revised guidance requiring every entity transition to the TB modifier by January 1, 2025.

Legislative Update

Administrative Dispute Resolution (ADR)



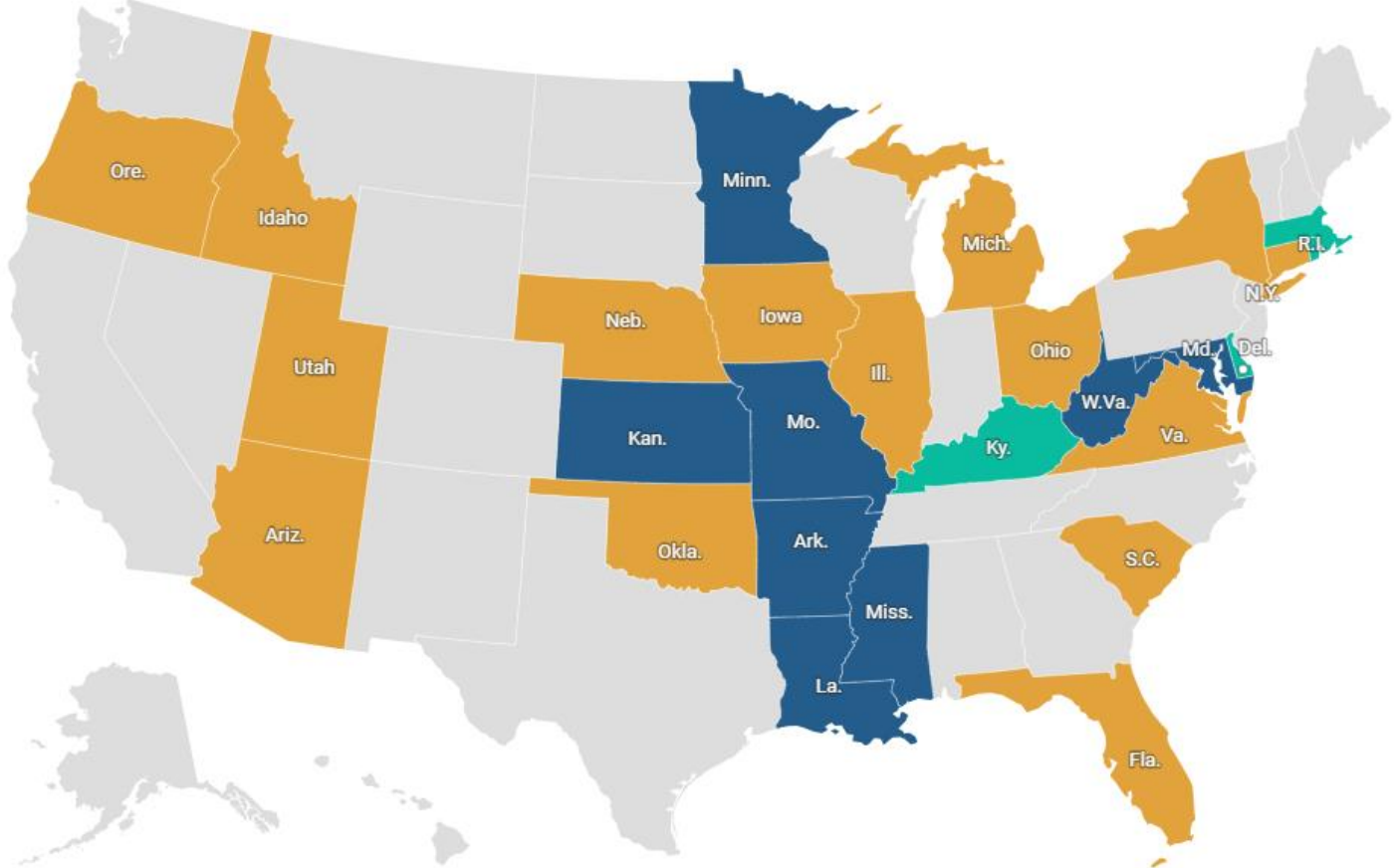
- 42 USC § 256b(d)(3) Administrative Dispute Resolution Process
- Rule created under the Affordable Care Act
 - Proposed rule not provided until 2016
- HHS issued final rule in 2020, though claims filed against rule leading to the new final rule being issued April 2024
- Final rule went into effect June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

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



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Map: updated as of July 16, 2024 - Created with Datawrapper

Legislative Update

Proposed Legislation

- Preserving Telehealth, Hospital, and Ambulance Access Act
- To amend title III of the Public Health Service Act to include rural emergency hospitals in the definition of a covered entity for purposes of the 340B drug discount program.
- The 340B PATIENTS Act of 2024
- Medicare PBM Accountability Act
- Lower Costs, More Transparency Act
- Real Education and Access for Healthy Youth Act of 2023.
- PATIENT Act of 2023
- To amend title III of the Public Health Service Act to ensure transparency and oversight of the 340B drug discount program
- MVP Act
- 340B Reporting and Accountability Act
- PROTECT 340B Act of 2023
- 340B Accountability Act of 2023
- Drug Pricing Transparency and Accountability Act

340B ACCESS Act

- Sponsored by Rep. Bucshon (R-Ind.)
- Limitations on participation and purchasing
- Patient definition
- Additional eligibility and reporting requirements

340B PATIENTS Act

- Sponsored by Rep. Matsui (D-Calif.)
- 5 additional democratic co-sponsors
- Contract pharmacy

SUSTAIN 340B Act

- Bipartisan

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)



Debbie Stabenow (D-MI)

Legislative Updates

Senator Cassidy Investigation



Contract Pharmacies

CVS Health
Walgreens



Hospitals

Bon Secours Mercy Health
Cleveland Clinic



Community Health Centers

Sun River Health
Yakima Valley Farm Workers Clinic

Visits With Congress



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

Advocacy Action Steps

1 Contact Congress and State Legislators

2 Work with advocacy groups

3 Report overcharges to HRSA

4 Educate your board

5 Maximize and maintain your 340B savings

Questions?



Contact

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