

FORVIS

340B Drug Pricing Program

This presentation should not be relied upon as legal advice

Meet the Presenters



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Lead Consultant



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FORV/S

An Enhanced Professional Services Firm

What's going to happen tomorrow? You can't predict the future, but you can prepare for it. To thrive in an environment that moves faster every day, business leaders need to anticipate and be ready for what comes next.

That's where **FORVIS** can help. Driven by a commitment to anticipating what's ahead, we aim to help our clients be ready when the future turns to the present. We're committed to using our exceptional vision to provide unmatched client experiences that drive business forward.

FORVIS was created by the merger of equals between BKD and DHG. We now have the scale and scope of a dynamic, Top-10 professional services firm—but we'll continue our legacy of high-touch personal service delivered with remarkable care, expertise, and drive.



8th

Largest US Firm



530+

Partners & Principals



5,500+

Team Members



10

Core Industries



70

Markets



28

States + UK
& Caymans



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social media



With national coverage and international presence, we're infinitely stronger: for us, for our clients, and for the market of the future.

Forward Vision Drives Our Unmatched Client Experiences

As a FORVIS client, you will benefit from a single organization with the enhanced capabilities of an expanded national platform, deepened industry expertise, greater resources, and innovative advisory services. Our aim is to help clients succeed today while preparing them to forge ahead into a clear future.

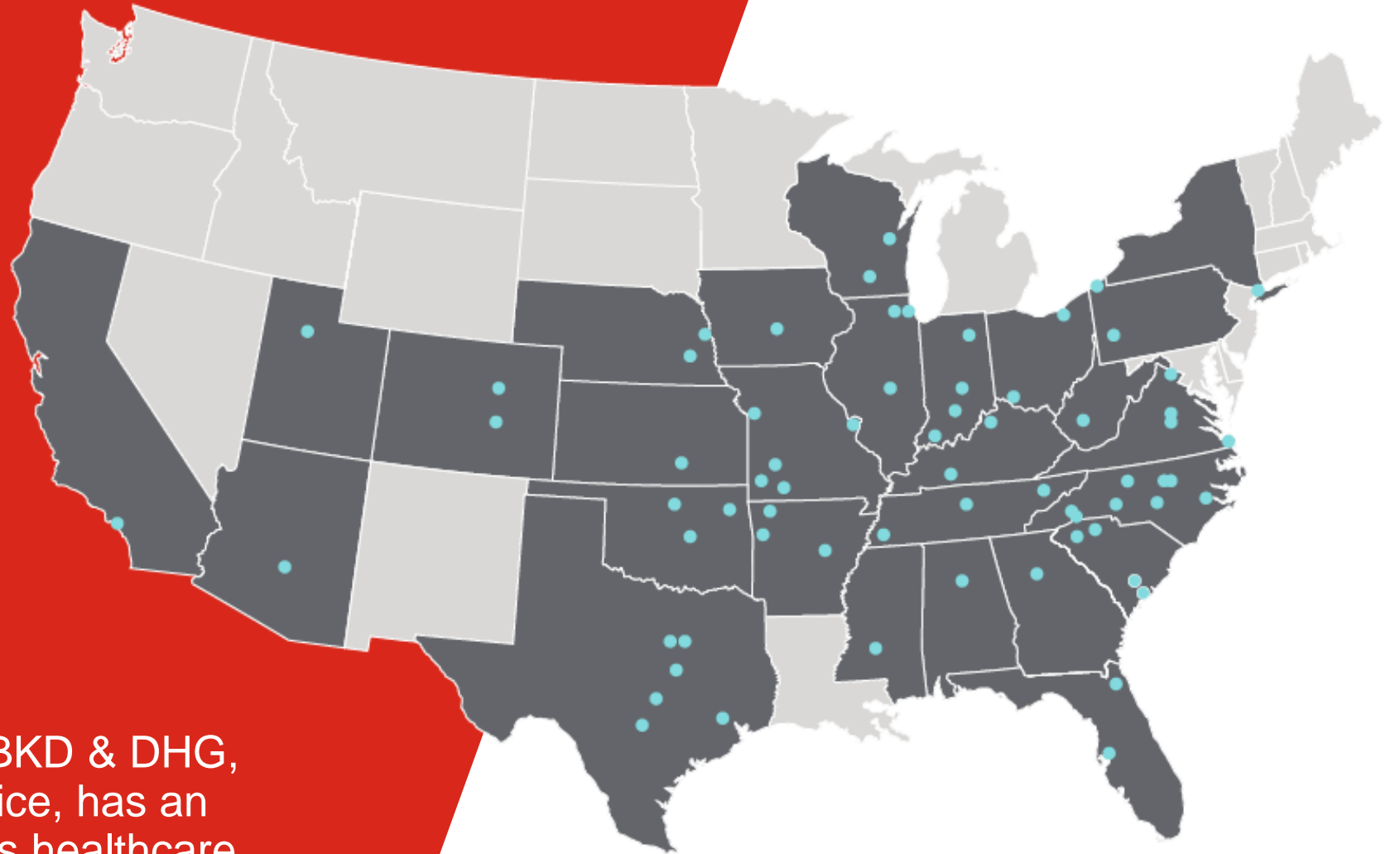
We are FORVIS — driven by a commitment to anticipate what's ahead so that our clients are ready to thrive when it arrives.



FORVIS Overview

A National Footprint

Created by the merger of BKD & DHG, FORVIS' Healthcare Practice, has an extensive reach that serves healthcare providers in all 50 states.



■ States with Clients Served ● States with Clients Served & Office Locations

Healthcare Consulting Practice Overview

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

FORVIS 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.



**Modern
Healthcare**



93%

Likelihood of
Clients to
Recommend

9th

Largest Healthcare
Consulting Firm
(2022)

90

Healthcare
Net Promoter
Score



Finance

Dynamic Financial Modeling, Financial System Optimization, Prospective Reporting & Feasibility Studies, and Payor Strategies



Reimbursement & Regulatory

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



Analytics

Market Intelligence Dashboards, Operational Insights, Value-Based Care Models, and Performance Benchmarking



Performance Improvement

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



Strategy

Mergers, Acquisitions & Partnerships, Organizational Health, Physician Alignment, Strategic Planning, and Value-Based Care

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AGENDA

- 340B Program Overview

- 340B Program Strategy

- Manufacturer Barriers

- 340B Program Outlook

340B Program Overview



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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**

Eligibility

	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

Diversions

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**

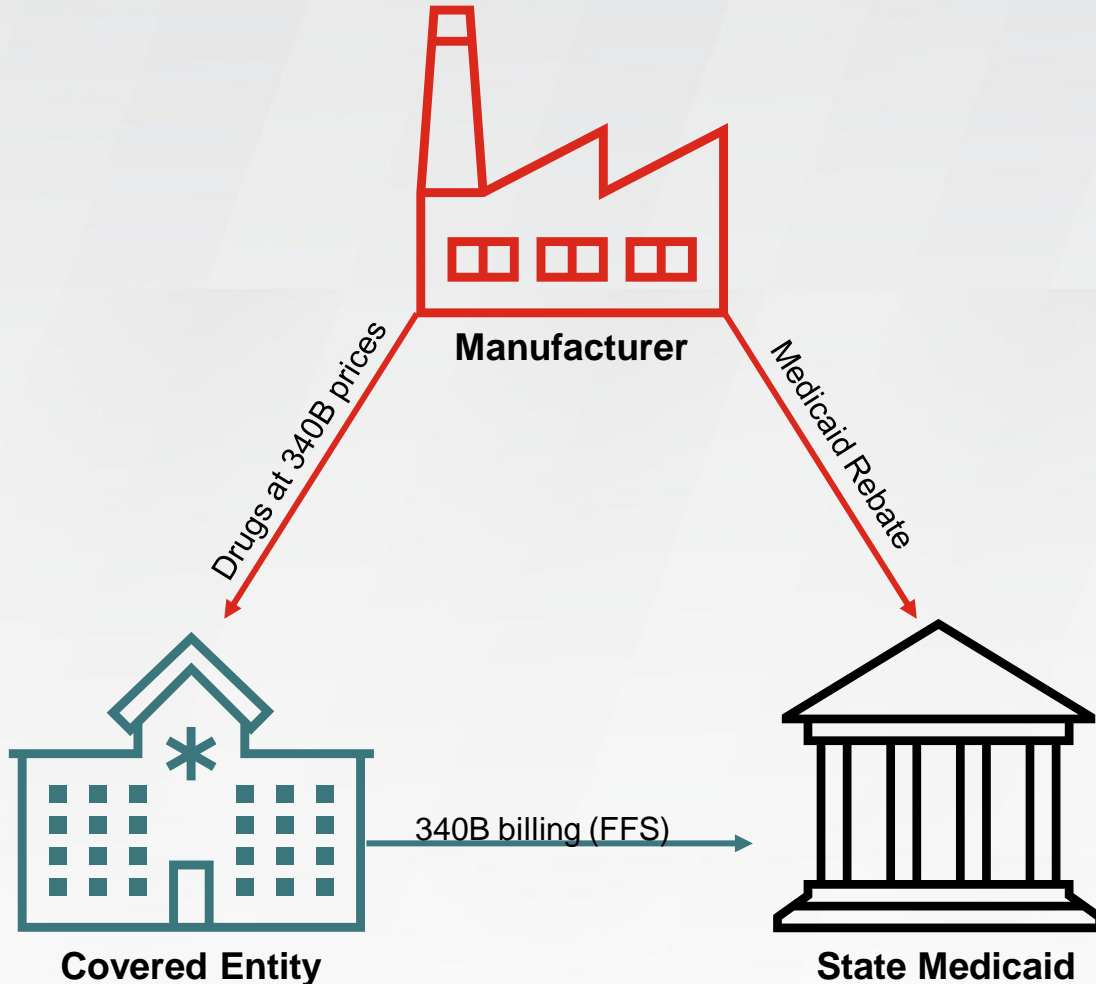
What is a **covered entity**?

- 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

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

HRSA has conducted approximately 200 audits annually since 2015

Results are publicly available

Audits initially had a collaborative/educational tone, but the tone has changed when HRSA began instituting punitive penalties to ensure compliance

HRSA audits conducted by the Bizzell Group or HRSA

HRSA will continue to focus on contract pharmacy arrangements, diversion, duplicate discounts, & 340B database records

Preparing for HRSA Audit

HRSA audit work procedures will include



Review of policies, procedures, & processes



Verification of internal controls to prevent diversion & duplicate discounts



Testing sample 340B-drug transactions

Results of HRSA Audit

Example Findings

- Incorrect 340B OPAIS Database Record
- Entity did not provide contract pharmacy oversight
- Diversion
- Duplicate Discounts
- Inaccurate or incomplete information in the Medicaid Exclusion File (MEF)
- Entity was billing Medicaid contrary to information included in the MEF

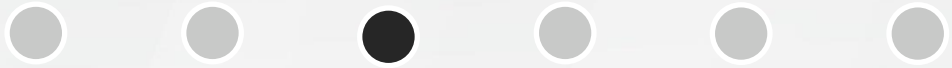
Consequences of Non-Compliance

- Repayment of discount to manufacturer (most common)
- Removal from 340B program
- Civil monetary penalties for knowing & intentional violations
- False claim liability

340B Oversight Action Steps

Procedure	Recommended Frequency
Diversion	Monthly
Duplicate Discount	Monthly
Prescriber List	As Needed/Monthly
Accumulations High/Low	Monthly
Purchase Activity/340B Savings	Monthly
Data Feeds	As Needed/Monthly
Qualification Filters	As Needed/Quarterly
HRSA OPAIS Database	As Needed/Quarterly

340B Program Strategy

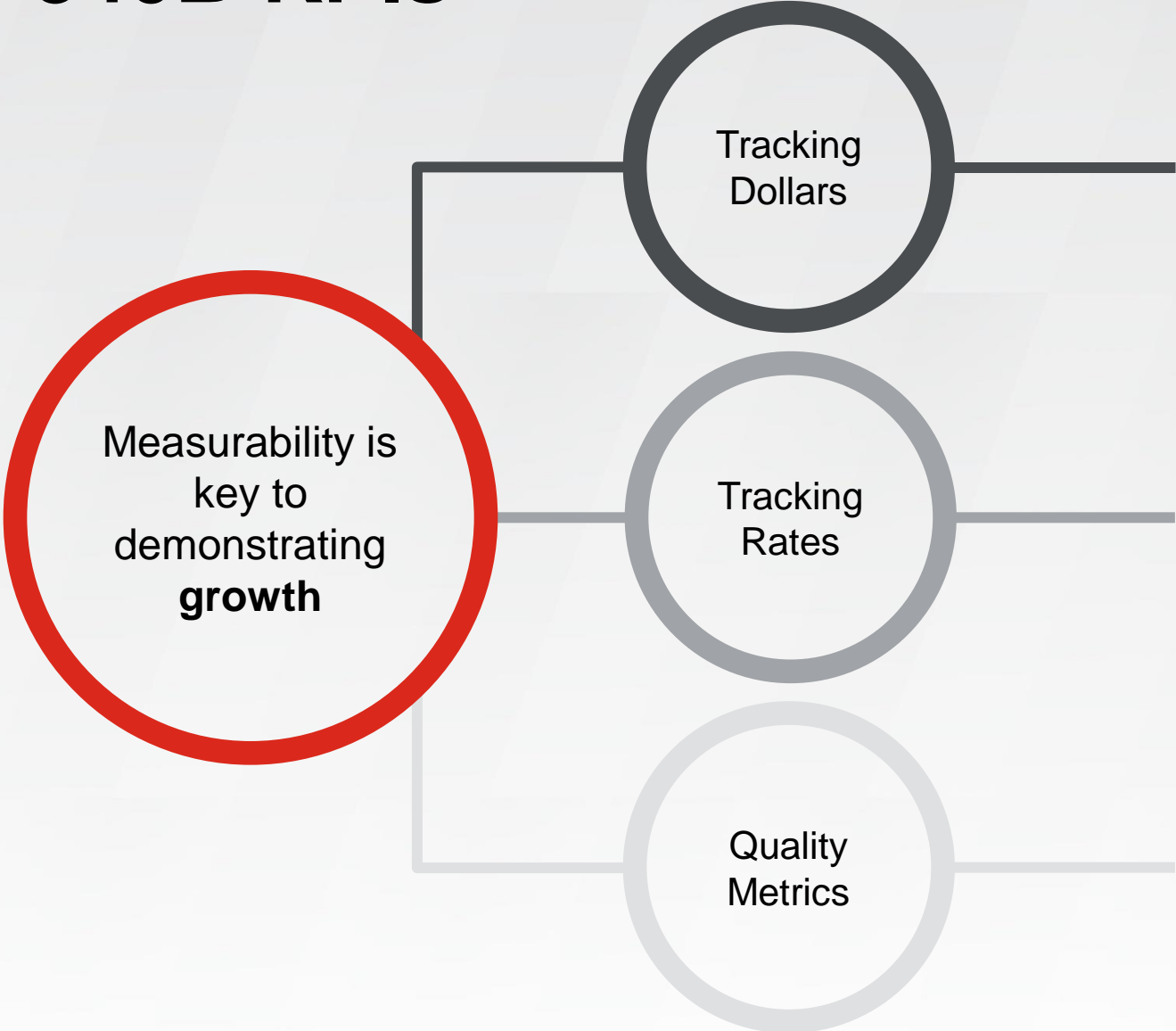


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340B Strategy – Approach

- 340B Oversight Committee
- 340B Team
- Policies & procedures
- Documented use of savings
- Internal monitoring
 - Medicaid BIN/PCN/Groups
 - Eligible locations
 - Contract pharmacy qualification parameters
- Internal audit
 - Mock audit procedures
 - Frequency & sample
- Independent external reviews
 - Operational
 - Compliance

340B KPIs



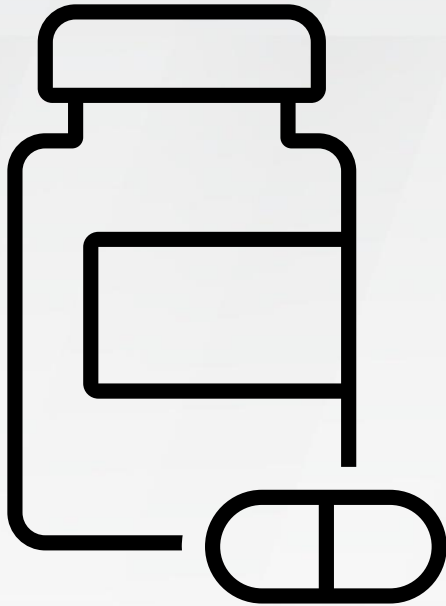
- 340B Revenue (Savings)
- 340B Purchases
- Provider Productivity & the Value of Prescriptions
- Capture Rate
- Participation Rate
- 340B and non-340B Spend
- Maintenance Medication Adherence
- Percentage of Refills Filled
- Social Determinants of Health

Top Opportunities

- Provider-Based Clinic Conversion
- 340B Drug Pricing Program
 - Contract Pharmacy Arrangement Expansion
 - Manufacturer Restrictions
 - 340B ESP
 - Alternative Distribution Model
 - Prescribing Trends
- Entity-Owned Retail Pharmacy
- Operational Improvements
- Pharmacy Charge Capture/Structure

Entity-Owned Pharmacy

Why it may be right for your hospital



Integrates directly with clinic staff and physicians
Ex. Prior authorizations and refill requests



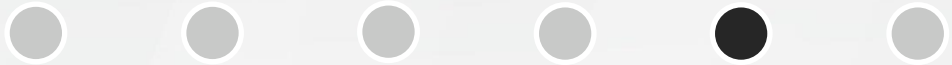
Financially bypass contract pharmacy issues
and service fees, manufacturer issues



Additional line of business with further potential
to grow

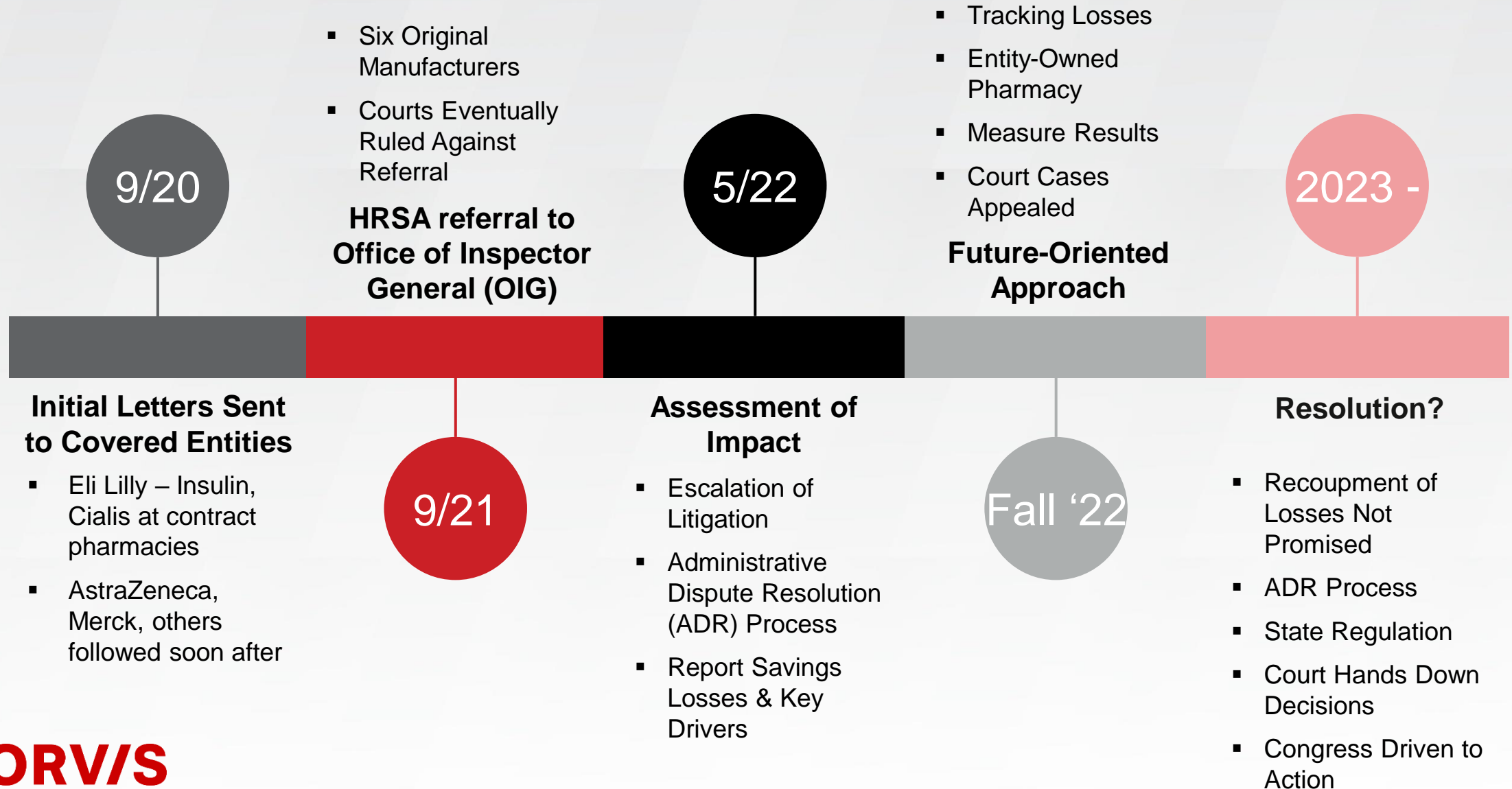
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Manufacturer Barriers



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The Manufacturer Timeline



Manufacturer Restrictions

As of November, 28 manufacturers have taken steps to unlawfully block and limit access to 340B savings

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)

340B ESP

Owned by Second Sight Solutions



Goal:
**Improve 340B
transparency**

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...”

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Should Data be Submitted to 340B ESP?



Duplicate discounts only apply to Medicaid FFS, but requests are for all claims



Understand HIPAA considerations



Consult with legal prior to responding



Assess financial impact of choosing not to submit claims & forfeiting 340B prices



Your entity may be eligible for an exception

Legal Action

District Courts

- 3 lawsuits across the districts
- 2 sided with manufacturers, 1 with covered entities
- All have been appealed

Court of Appeals

- Novartis / United Therapeutics v. HHS in District of Columbia
- Eli Lilly v. HHS in 7th Circuit
- Sanofi / Novo Nordisk / AstraZeneca v. HHS in 3rd Circuit

Supreme Court

- May end up in Supreme Court if Appeals issue diverging opinions
 - 3rd Circuit sided with manufacturers
 - Other 2 cases are pending

Legal Action, Cont.

Legislation passed in AR and LA **prohibits** manufacturers (& other 3rd parties) from:



ARKANSAS

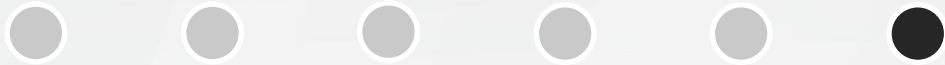
Implementing discriminatory fees for 340B participants

Requiring claims modifiers to identify 340B drugs

Restricting access to 340B drugs through additional contract pharmacy requirements

LOUISIANA

340B Program Outlook

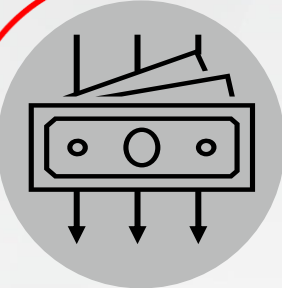


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OPPS Remedy Timeline

CMS releases Final Rule, reducing Medicare payment for most 340B drugs



January 2018

December 2018



Hospital groups sue CMS over the payment cuts

US Supreme Court rules that cuts were illegal in 2018 & 2019



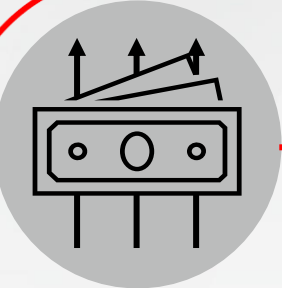
June 2022

September 2022



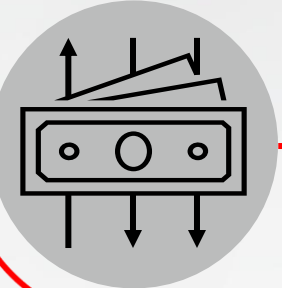
Federal District Judge rules that cuts were illegal in 2020-2022

CMS resumes paying hospitals at ASP + 6% (equal to rate prior to the cuts)



September 2023


November 2023



CMS finalizes rule for a lump sum payment, cutting future payments as an offset



OPPS Remedy – Action Steps



Assess
Remedy
proposed
lump sum for
Medicare
Traditional

Assess
Medicare
Advantage
potential lump
sum payment
and contract
terms to see if
allows for
retrospective
payment

Revenue
Recognition –
no current
needs until
rule is
finalized

Budget for
ASP + 6% and
0.5%
reduction for
other services

Unregistered Child Sites

(Oct. 2023) HRSA announces that they will be prohibiting the use of 340B drugs at unregistered child sites. Organizations have two paths to compliance:

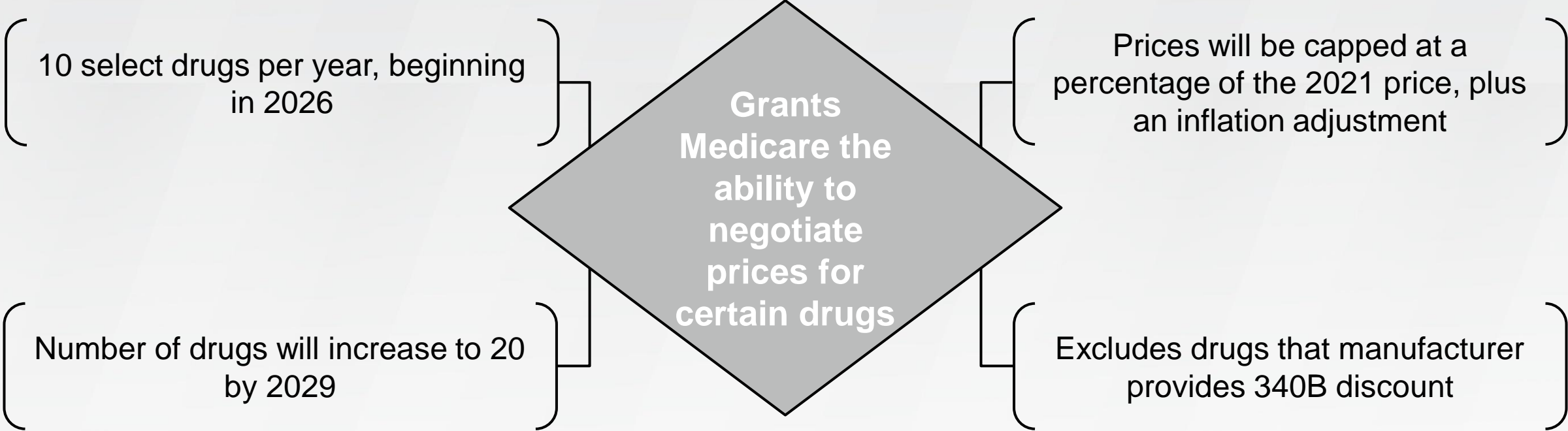
Hospitals with sites already on their MCR but not on OPAIS, must register the sites on OPAIS during the next registration window (Jan 1. -16)

Hospitals with sites *not* on the MCR nor OPAIS, must submit the following information to HRSA by January 25, 2024:

1. Name of child site
2. Date the site will be listed on the MCR – which must be the next one filed
3. The date the hospital will register the site on OPAIS

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

Inflation Reduction Act



*Additional component of Act fines manufacturers who raise drug prices at a rate greater than inflation

Visits with Congress

15 Congressional offices

Focus on key decision makers

Advocacy organizations

“Good” and “bad” players

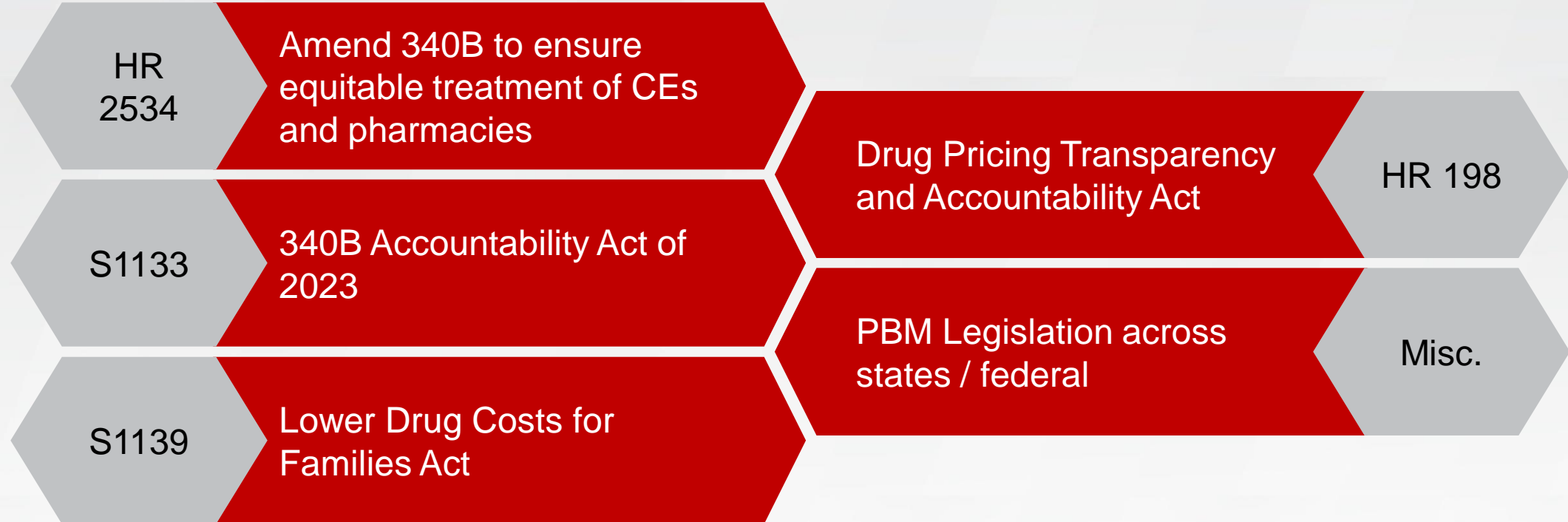
Will need compromise between all 340B parties

Watching for future rule changes

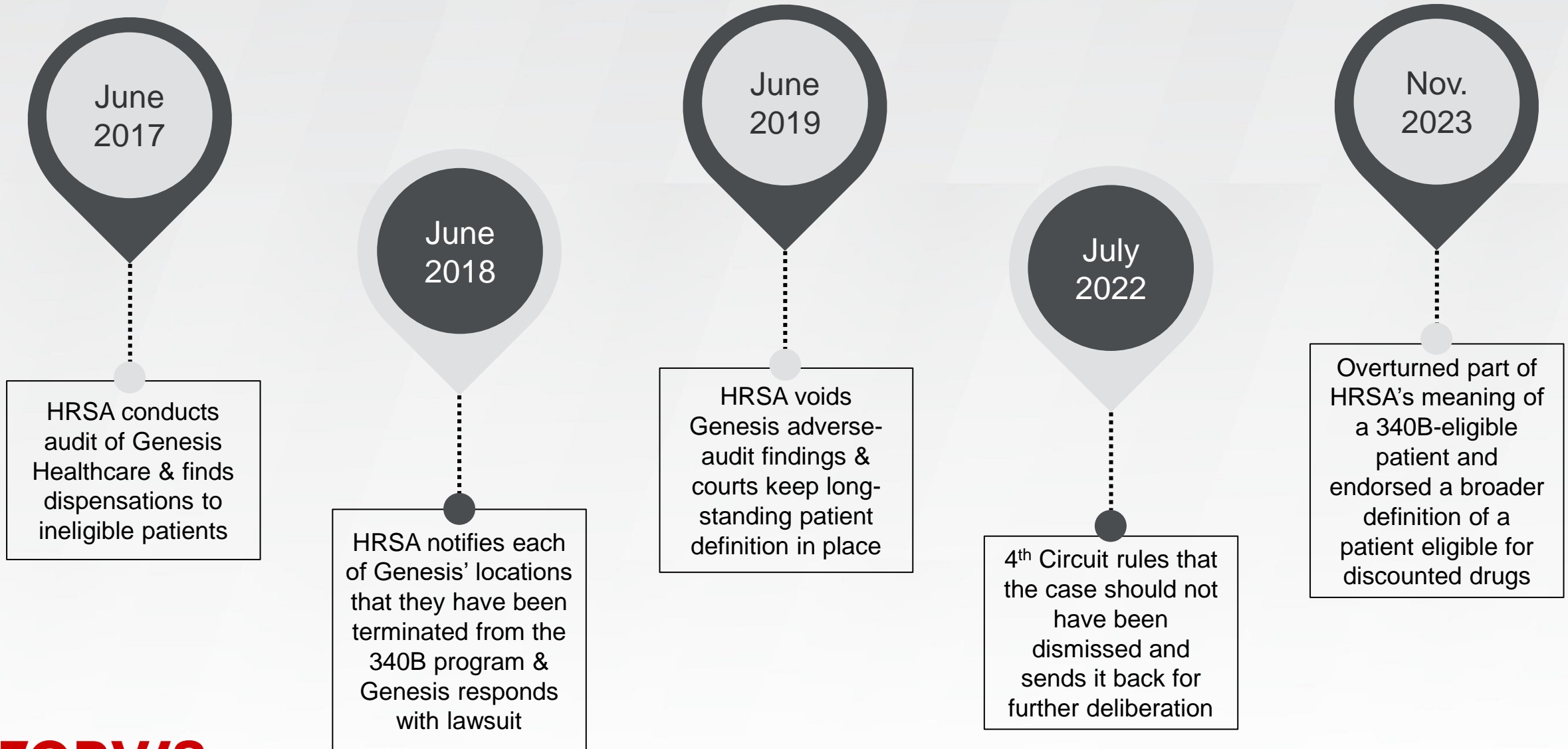


Legislative Update

Pharmacy-Related Bills



Genesis Healthcare v. Becerra



New 340B Regulation

- Restrictions to use and number of contract pharmacies
- Changes to hospital eligibility, including child sites
- Contract pharmacy definition
- Mega guidance
- Report on use of 340B savings
- Provide HRSA with regulatory authority to administer 340B
- Discriminatory pricing

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

Thank you!

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