

# FORVIS

## **340B Drug Pricing Program Changes and Challenges**

*This presentation should not be relied upon as legal advice*

# Meet the Presenter



**Brian Bell**

Managing Director

## 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.



**8<sup>th</sup>**

Largest US Firm



**530+**

Partners & Principals



**5,500+**

Team Members



**10**

Core Industries



**70**

Markets



**28**

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& Caymans



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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.

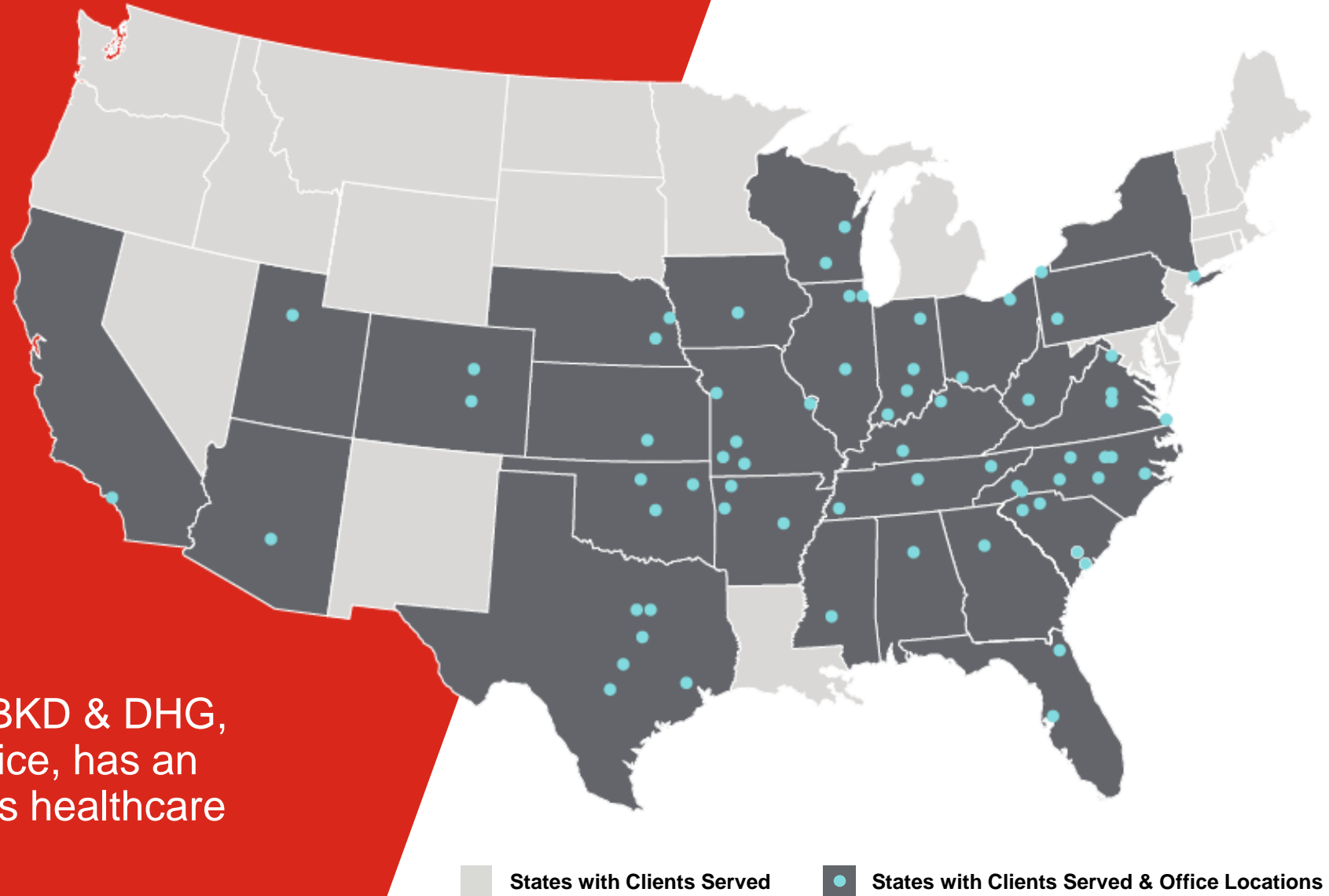
We are FORVIS — driven by a commitment to anticipate what's ahead so that our clients are ready to thrive when it arrives.



# FORVIS Overview

## A National Footprint

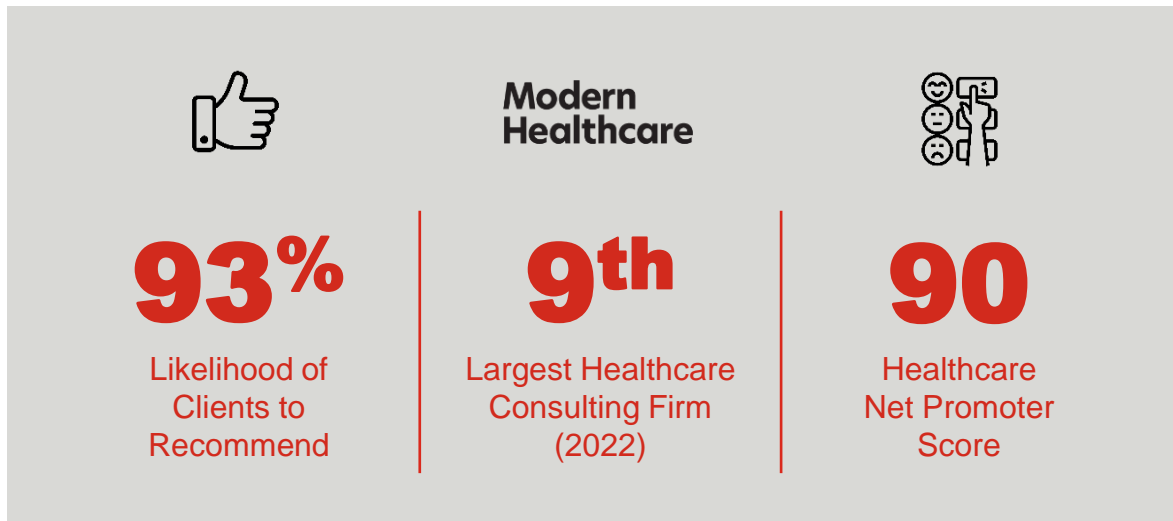
Created by the merger of BKD & DHG, FORVIS' Healthcare Practice, has an extensive reach that serves healthcare providers in all 50 states.



# 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.



Sources: Modern Healthcare's Largest Management Consulting Firms 2022 ranking and UCX survey NPS 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

# AGENDA

- 340B Overview
- 340B Compliance Pillars
- 340B HRSA Audits
- 340B Strategy
- 340B Manufacturer Attacks
- 340B Outlook

# Initial Thoughts

- New 340B rules, regulations, & strategies are being considered frequently
- What will the 340B program look like in future years?
- How can hospitals plan for the future with so much uncertainty?
- It is possible that the potential changes in the 340B pharmacy program will not come to fruition, but today we would like to explain why hoping for that outcome & doing nothing to plan may not be the best course of action

# 340B Overview

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# 340B Drug Pricing Program Overview

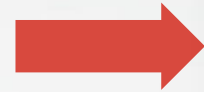


- Federally mandated drug pricing program created in 1992
  - Bi-partisan Congress, Signed by George H.W. Bush
- 2022 marks the 30th anniversary of the program
- Part of Public Health Service Act, section 340B & Medicaid rebate program
  - Drug manufacturers must provide front-end discounts on covered outpatient drugs purchased by covered entities
- Provides discounts on outpatient drugs purchased by “safety net” providers for eligible patients
  - Intended to provide financial relief to facilities that provide care to medically underserved
- 340B expansion under President Clinton, President Bush, & President Obama
- Average savings of 25%–50% for eligible covered entities on outpatient drugs

# 340B Drug Pricing Program Overview

How are covered entities using 340B savings?

Provide discounts  
on drugs to patients



Expand services by  
provider to patients



Provide services to  
more patients

# 340B Compliance Pillars

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# 340B Compliance



# 340B Patient Definition

- For a patient to be eligible for 340B in a hospital setting they must:
  - Be an outpatient at the time the drug is administered
  - Receive the drug in a reimbursable cost center on Worksheet A
  - Receive the care from an employed or contracted clinician
  - Have a record at the hospital of the care provided
- For a patient to be eligible for 340B in a retail pharmacy setting they must:
  - Have received care from the hospital in a reimbursable cost center on Worksheet A
  - The drug must be related to the care provided by the hospital (responsibility for the care)
  - Receive the care from an employed or contracted clinician
  - Have a record at the hospital of the care provided

# Diversions

## Diversions

- Drugs can only be used on an outpatient basis for covered entity's patients as defined by HRSA
- Use for other individuals constitutes prohibited diversion
- Focus on defining "patient" & "covered entity"

## What is "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

# 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
- General options for covered entities
  - Carve-out Medicaid - from 340B drug purchases
  - Carve-in Medicaid - requires verifying Medicaid exclusion file is accurate in 340B OPAIS
- 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)
  - Contract pharmacies should not “Carve-in” Medicaid FFS & should review state guidance & consult with legal on Medicaid MCO

**\*The responsibility for avoiding duplicate discount is on the covered entity**

# Medicaid Apexus Tool

## Maine Medicaid Contact Details

### Technical contact

DHHS OFFICE OF MAINECARE SERVICES

JAN WRIGHT

[JAN.WRIGHT@MAINE.GOV](mailto:JAN.WRIGHT@MAINE.GOV)

STATE HOUSE STATION #11 109 CAPITOL ...

AUGUSTA, ME 04333-0011

(207) 624-4052

### Rebate contact

MAINE DHHS

JAN WRIGHT

[JAN.WRIGHT@MAINE.GOV](mailto:JAN.WRIGHT@MAINE.GOV)

STATE HOUSE STATION #11 109 CAPITOL ...

AUGUSTA, ME 04333-0011

(207) 624-4052

### Policy contact

DHHS OFFICE OF MAINECARE SERVICES

ANNE-MARIE TODERICO, PHARMD

[ANNEMARIE.TODERICO@MAINE.GOV](mailto:ANNEMARIE.TODERICO@MAINE.GOV)

STATE HOUSE STATION #11 109 CAPITOL ...

AUGUSTA, ME 04333-0011

(207) 624-6948

### Retail Pharmacy Transactions - Fee For Service (FFS)

#### Drug Cost (submissions)

Drug cost type when 340B drugs are dispensed.

PVP unable to find source info to validate data. Please click here if you can provide help.

#### Drug Cost (reimbursements)

Drug cost type state plans reimburse at for 340B dispenses.

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#### Required Claim Identifiers

Claim identifiers required to indicate 340B drugs were dispensed.

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#### Professional Dispensing Fee (PDF)

The current professional dispensing fee for FFS 340B claims. Note: some states have ranges based on different factors.

PVP unable to find source info to validate data. Please click here if you can provide help.

### Provider or Facility Administered Transactions Fee For Service (FFS)

#### Drug Cost (submissions)

Drug cost type when 340B drugs are administered.

Usual and customary rate (U&C)

#### Drug Cost (reimbursements)

Drug cost type state plans reimburse at for 340B dispenses.

340B Actual Acquisition Cost (AAC)

#### Required Claim Identifiers

Claim identifiers required to indicate 340B drugs were administered.

Follow Medicare "JG" or "TB" requirements

#### Comments/Notes

340B Claims Reconciliation Process:

#### Contract Pharmacies\*

Dispensing 340B drugs through contract pharmacy is explicitly prohibited by state.

\* Despite Federal position on dispensing through CP arrangements

#### Medicaid Managed Care Organization (MCO) Information

State uses MCO plans?  
Does the state use MCO(s) to manage Medicaid services?

No



# Contract Pharmacy

- HRSA allows providers to enter arrangements with multiple contract pharmacies to dispense 340B drugs to qualifying patients of providers
- Covered entity is responsible for compliance & must monitor contract pharmacies
- HRSA recommends independent audits
- Child sites, outpatient clinics
- Retail pharmacy split-billing software
- Brand vs. generic
- Do you periodically review your contract pharmacy arrangements?

# 340B HRSA Audits

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# 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

# Example Audit Findings

- Incorrect 340B OPAIS Database Record
- Entity did not provide contract pharmacy oversight
- Diversion
  - 340B drugs dispensed at contract pharmacy for prescriptions written at ineligible sites
  - 340B drug dispensed to inpatient; 340B drugs dispensed at contract pharmacies, not supported by a medical record
  - 340B drugs were not properly accumulated
- Duplicate Discounts
- “Inaccurate or incomplete information in the Medicaid Exclusion File”
- Entity was billing Medicaid contrary to information included in the Medicaid Exclusion File

# 340B Oversight Committee

- 340B program staff conduct internal reviews with a goal of sharing issues of non-compliance & deviations in
  - Volume Trends
  - Expected payment amounts
  - Price changes & purchase invoices
- HRSA recommends an active 340B Oversight Committee regularly review issues & “assesses if the results are indicative of a material breach” according to Health Center policy to uphold program integrity

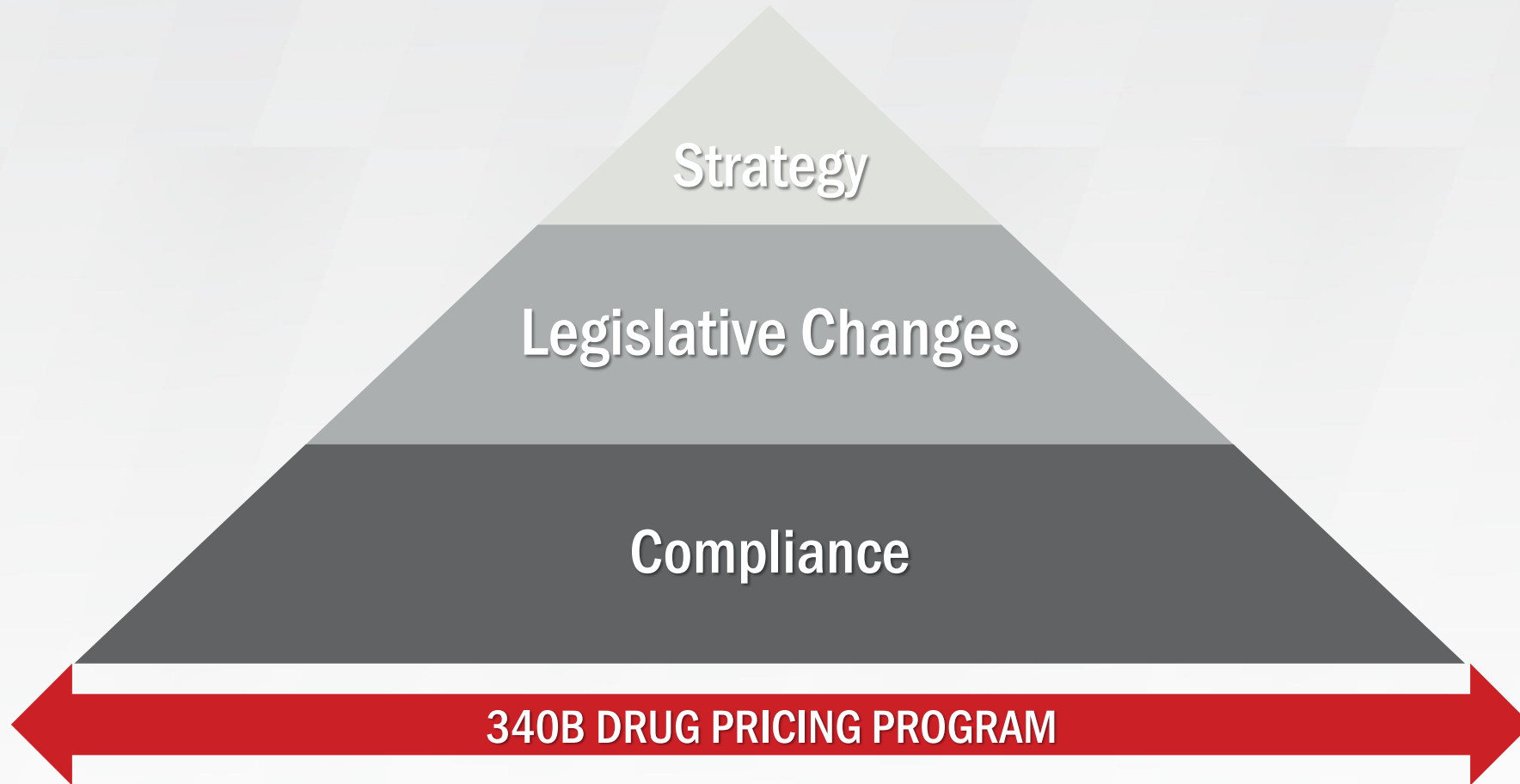
# 340B Strategy

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# 340B Strategy



# 340B KPIs

- Measurability is key to demonstrating growth
  - Tracking of dollars over time
    - > 340B Revenue (Savings)
    - > 340B Purchases
    - > Provider productivity – the values of prescriptions from your top providers
  - Tracking of rates over time
    - > Capture rate
    - > Participation rate
    - > 340B & non-340B account spend – % of 340B compared to non-340B purchases
  - Quality Metrics
    - > Medication adherence –
      - maintenance medications for diabetes, blood pressure, asthma, etc. are relatively predictable & indicative of future growth
      - First fill/Refill % fills
    - > Social Determinants of Health – mail order 340B medications do not require transit cost



# 340B Software

Virtual Inventory

Receive discounts based on the drug utilization by covered outpatients

Retrospective procurement is used to realize the discounts based on utilization

Can be used for Mixed Use & Contract Pharmacy

# 340B Strategy – Approach

- 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 Strategy – Apexus

- 340B Prime Vendor Program (PVP)
- Contract awarded by HRSA
- Contracts with manufacturers & distributors
  - Contracting
  - Distribution
- Manufacturer refund service
- 340B Education
  - Technical Assistance

# Entity-Owned Pharmacy

- **Why** an entity-owned Pharmacy might be right for your hospital
  - Integrates directly with clinic staff & physicians
    - + Prior authorizations
    - + Refills, substitutions
    - + Polypharmacy
  - Financially bypasses contract pharmacy issues & service fees
  - Additional line of business with further potential to grow (specialty, limited distribution drug access)

# Entity-Owned Pharmacy

- **How** an entity-owned Pharmacy might be right for your hospital
  - Begin by assess factors & costs to create a business plan
    - + Location, space allotment
    - + Build-out costs
    - + Fixed costs, initial inventory, salaries
    - + Financial projections
      - > How soon after opening do you expect to generate a profit?
      - > Current electronic prescribing volume

# Entity-Owned Pharmacy

- Critical Considerations for an entity-owned Pharmacy
  - Closed-door vs. open-door
  - Mail order, delivery, alternative delivery sites
  - Partnering with a pharmacy manager for a turnkey outcome (software, staffing, architecture)
  - Marketing
  - Entity-owned pharmacies are not always profitable. Clinical services offered & marketing strategies can be a part of a competitive analysis

# Top Opportunities

- 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
- Provider-Based Clinic Conversion

# Manufacturer Barriers

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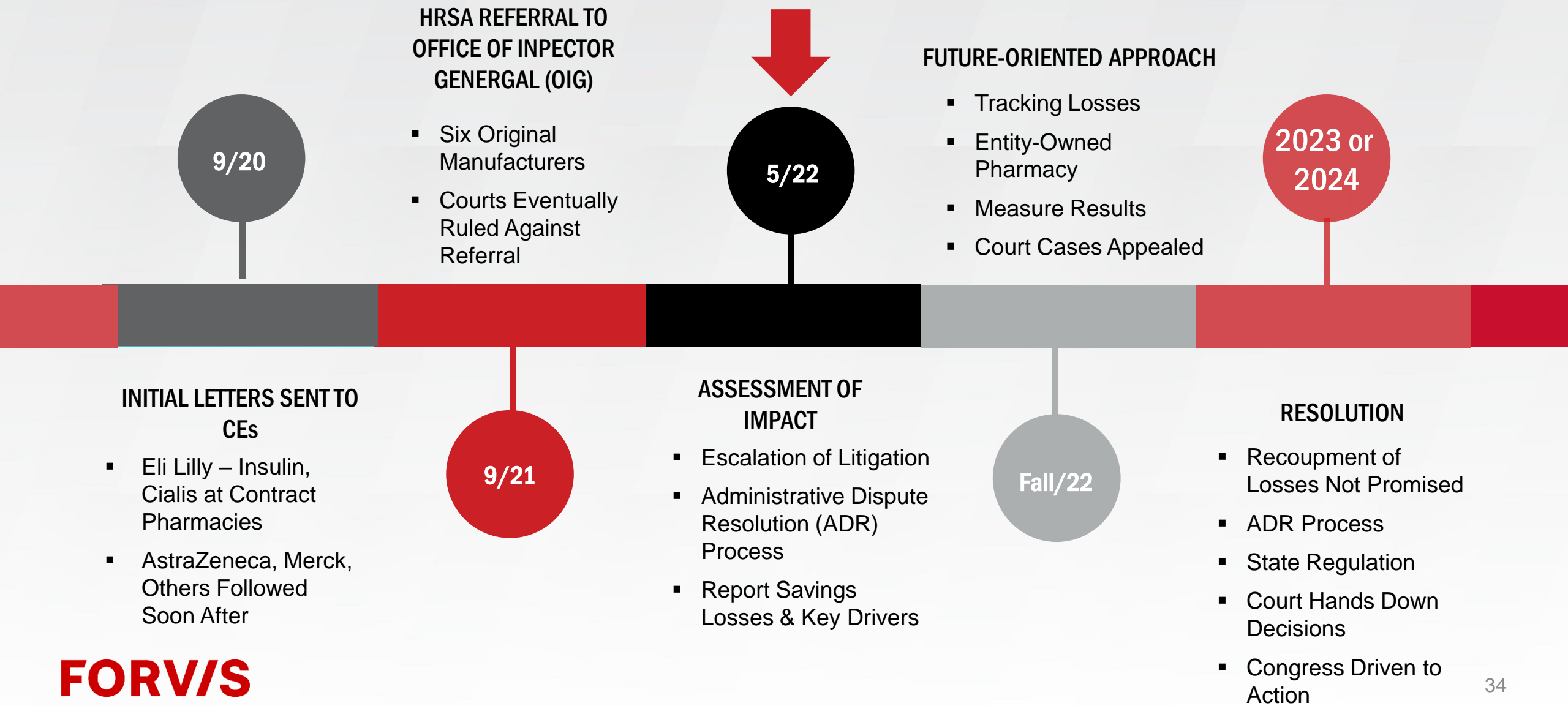
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# Big Pharma

RANK	COMPANY	HEADQUARTERS	2021 REVENUES (\$USD)
1	<a href="#">Pfizer</a>	United States	\$81,288,000,000
2	<a href="#">Sinopharm (pharmaceutical distribution segment)</a>	China	\$60,450,609,227
3	<a href="#">AbbVie</a>	United States	\$56,197,000,000
4	<a href="#">Janssen (Johnson &amp; Johnson's pharmaceutical segment)</a>	United States	\$52,080,000,000
5	<a href="#">Novartis</a>	Switzerland	\$51,626,000,000
6	<a href="#">Roche Pharmaceuticals (division of Roche Group)</a>	Switzerland	\$49,257,436,570
7	<a href="#">Merck &amp; Co.</a>	United States	\$48,704,000,000
8	<a href="#">GlaxoSmithKline (GSK) (minus consumer segment)</a>	United Kingdom	\$46,940,864,000
9	<a href="#">Bristol Myers Squibb</a>	United States	\$46,385,000,000
10	<a href="#">Sanofi</a>	France	\$44,557,980,000
11	<a href="#">AstraZeneca</a>	United Kingdom	\$37,417,000,000
12	<a href="#">Thermo Fisher Scientific (Life Sciences Solutions + Laboratory Products and Biopharma Services)</a>	United States	\$30,493,000,000
13	<a href="#">Takeda Pharmaceutical</a>	Japan	\$29,113,364,894
14	<a href="#">Eli Lilly</a>	United States	\$28,318,400,000
15	<a href="#">Gilead Sciences</a>	United States	\$27,305,000,000
16	<a href="#">Amgen</a>	United States	\$25,979,000,000
17	<a href="#">Boehringer Ingelheim</a>	Germany	\$24,391,094,000
18	<a href="#">BioNTech</a>	Germany	\$22,449,436,100
19	<a href="#">Novo Nordisk</a>	Denmark	\$22,420,382,166
20	<a href="#">Bayer (Pharmaceuticals Division)</a>	Germany	\$21,651,820,000

# The Manufacturer Timeline



# Manufacturer Challenges

- 24 manufacturers have unlawfully taken away 340B savings
- Average reduction in contract pharmacy benefit due to manufacturer restrictions
  - Community Health Center (CHC) – 30% (per client experience, expected to increase)
  - Per 340B Health
    - Critical Access Hospitals (CAH) – 39%
    - DSH/RRC/SCH – 23%
    - Urban hospitals – \$2.2M in losses on average
    - CAH - \$450,000 in losses on average
    - 75% of hospitals making cuts
    - 33% of hospitals at risk of closure (mostly small/rural)

# Refusing 340B Pricing – Contract Pharmacies

- Submit claims data for access to contract pharmacies
- Single designation contract pharmacy if no entity-owned pharmacy
- Single designation contract pharmacy
- Distance requirements
- Specific drugs
- No 340B pricing for contract pharmacy

# 340B ESP

- Owned by Second Sight Solutions
  - 340B ESP CEO and Founder Aaron Vandervelde – Managing Director Berkeley Research Group
- Allows 340B covered entities & manufacturers to work collaboratively to resolve duplicate discounts
- Improve 340B transparency
  - Intent is not to hard cover entities but to prevent ineligible rebates to third-party payers
  - Only works if statutory protection against discriminatory reimbursement practices
- Claims data for all payers
- What are they going to do with the data?
- 340B ESP trainer: *“You have to remember that the manufacturer’s view of duplicate discounts is different than that of a covered entity...”*
- Concerns with terms of use

# Should Data be Submitted to 340B ESP

- Duplicate discount applies to Medicaid Fee for Service; however, manufacturer requests are asking for all claims for manufacturer
- Many covered entities are choosing not to respond or are responding with legal input
- Request exceptions
- Speak with legal counsel prior to responding
- Understand HIPAA considerations / violation
- Assess potential financial impact if manufacturer does not offer 340B pricing
- Contract Pharmacy/Supply Chain non-disclosures
- Mid-term elections & Congress
- Short Term Gain, Long Term Pain

# Kalderos – Duplicate Discount Requests

- Contacting covered entities requesting data
- Should covered entities reply?

# Civil Monetary Penalties

- HRSA has referred drug companies to OIG
- Potential fines for their continued violations of federal law required 340B discounts on eligible drugs dispensed at community pharmacies
- If OIG determines the drug companies knowingly & intentionally overcharged safety-net providers, it can assess civil monetary penalties that can total nearly \$6,000 per violation
- Courts have ruled against violation letters
- Support of Congress



# 340B Outlook

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# OPPS Remedy

- Background
  - January 2018 – September 2022 – Hospitals received ASP – 22.5% for 340B acquired Status Indicator K Drugs identified with JG Modifier for Medicare Traditional and Medicare Advantage
    - + Included DSH, RRC and Urban SCH
    - > Excluded CAH and Rural SCH
  - Hospital groups sued CMS
  - June 2022 – U.S. Supreme Court ruled that the cuts were illegal for 2018 and 2019
    - + September 2022 – Federal District Judge ruled that the cuts were illegal for 2020-2022
  - CMS resumed paying hospitals ASP + 6% in September 2023

# OPPS Remedy

- CMS requested re-billing for January 2022-September 2022 to gain ASP +6% reimbursement for Medicare Traditional
- Medicare Advantage was not discussed in proposed rule
  - Medicare Advantage should have resumed payments to ASP +6% for CY 2023
    - + Review that this is occurring
- Lump sum payment for CY 2018-2022 for affected hospitals (1,600 hospitals)
- Budget neutrality – \$7.8 Billion
  - OPPS conversion factor minus 0.5% starting CY 2015 for other services for all hospitals for not just 340B covered entities. Offset \$7.8 Billion over 16 years

# OPPS Remedy

- 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
  - Contact MA plans for resolution
  - Litigation?
- Comment on proposed rule by September 5, 2023
- Revenue Recognition – no current needs until rule is finalized
- Budget for ASP + 6% and 0.5% reduction for other services

# Modifiers for all 340B Covered Entities

- All 340B covered entities including hospitals and non-hospitals require modifiers
  - Separately payable Part B drugs and biologicals
  - January 1, 2024

Designation	Modifier
DSH, RRC, non-rural SCH	JG
PED, CAN, rural SCH	TB
Grantee (including RW and HM clinics)	JG
CAH	Not determined

# Visits with Congress

- 15 Congressional offices
  - Focus on key decision makers (Senate Finance/HELP, House Ways and Means)
- Good and bad players
- Advocacy organizations
- Need compromise for all involved with 340B
  - CEs, Payers, Manufacturers, Patients
- Transparency
- Future rule changes
- Advocacy
- Future visits



# Legislative Update

- HRSA Unregistered Child Site FAQ removal
- PHE End 5/11/2023
  - Immediate registration waiver
- Patient Definition
- Manufacturer Restrictions
  - State laws – Louisiana (Merck and Teva), Arkansas (Merck)
  - Court Cases
  - Will Congress act?
- Pharmacy Bills
  - HR 2534 – To amend 340B to ensure equitable treatment of CEs and pharmacies
  - S1133 – 340B Accountability Act of 2023
  - S1139 – Lower Drug Costs for Families Act
  - HR 198 Drug Pricing Transparency and Accountability Act
  - PBM Legislation – Federal/State
- NACHC
  - ASAP 340B
  - 340C

# 2023 Outlook – Lawsuits

- **District Courts**
  - 3 rulings
  - All have been appealed
- **Appeals Courts**
  - Novartis/United Therapeutics v. HHS in the U.S. Court of Appeals for the District of Columbia Circuit
  - Eli Lilly v. HHS in the U.S. Court of Appeals for the 7th Circuit in Chicago
  - Sanofi /Novo Nordisk /AstraZeneca v. HHS before the U.S. Court of Appeals for the 3rd Circuit in Philadelphia
- **Supreme Court**
  - Will this case be heard in Supreme Court in 2023/2024?
  - 100 cases per year
  - CEs can't sue manufacturers





# Inflation Reduction Act

- Grants Medicare the ability to negotiate prices on some drugs
- Starting in 2026, negotiate drug prices for 10 drugs per year
- Number of drugs will increase to 20 per year by 2029 and incorporate drugs in Parts B and D
- Negotiated prices are capped as a percentage of the drug's price in 2021 adjust for inflation
  - For future drugs as a percentage of the launch price
- Excludes drugs that manufacturer provides 340B Discount
- Negotiated prices are considered “best price” for purposes of Medicaid and 340B
- Penalties for price increases over inflation

# Genesis Healthcare v. Becerra

- 340B Patient Definition
- Audit finding
  - Dispensations to ineligible individuals, not able to participate in 340B
  - Genesis sued HRSA
  - 1996 patient definition inconsistent with 340B regulation
- US Court of Appeals for the Fourth Circuit sent case back to Federal District Court
  - Address patient definition and determine patient definition
  - Additional guidance and clarification
- Waiting on ruling

# 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!

**Brian Bell**  
**Managing Director**  
**[brian.bell@forvis.com](mailto:brian.bell@forvis.com)**

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