



The 340B Crossroads: Dead End or Defining Moment?

Mike Summers MHSA, 340B ACE

08/29/2025





Disclosure

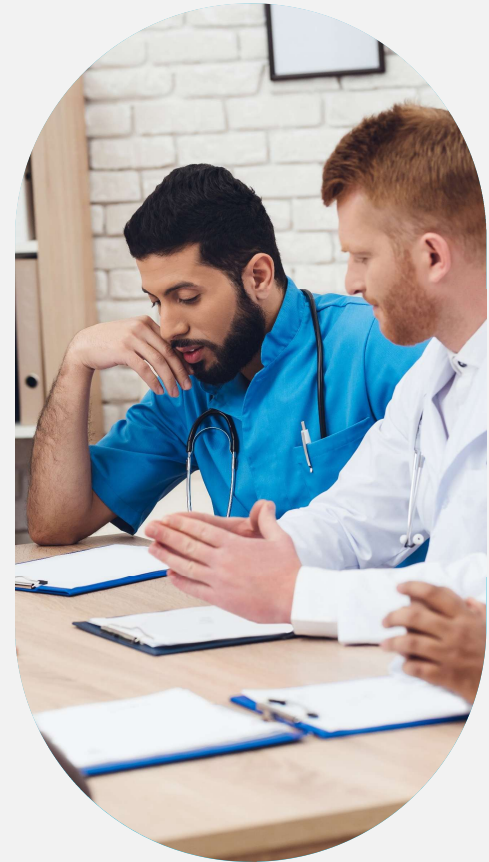
Nothing in this presentation should be constituted as legal advice.

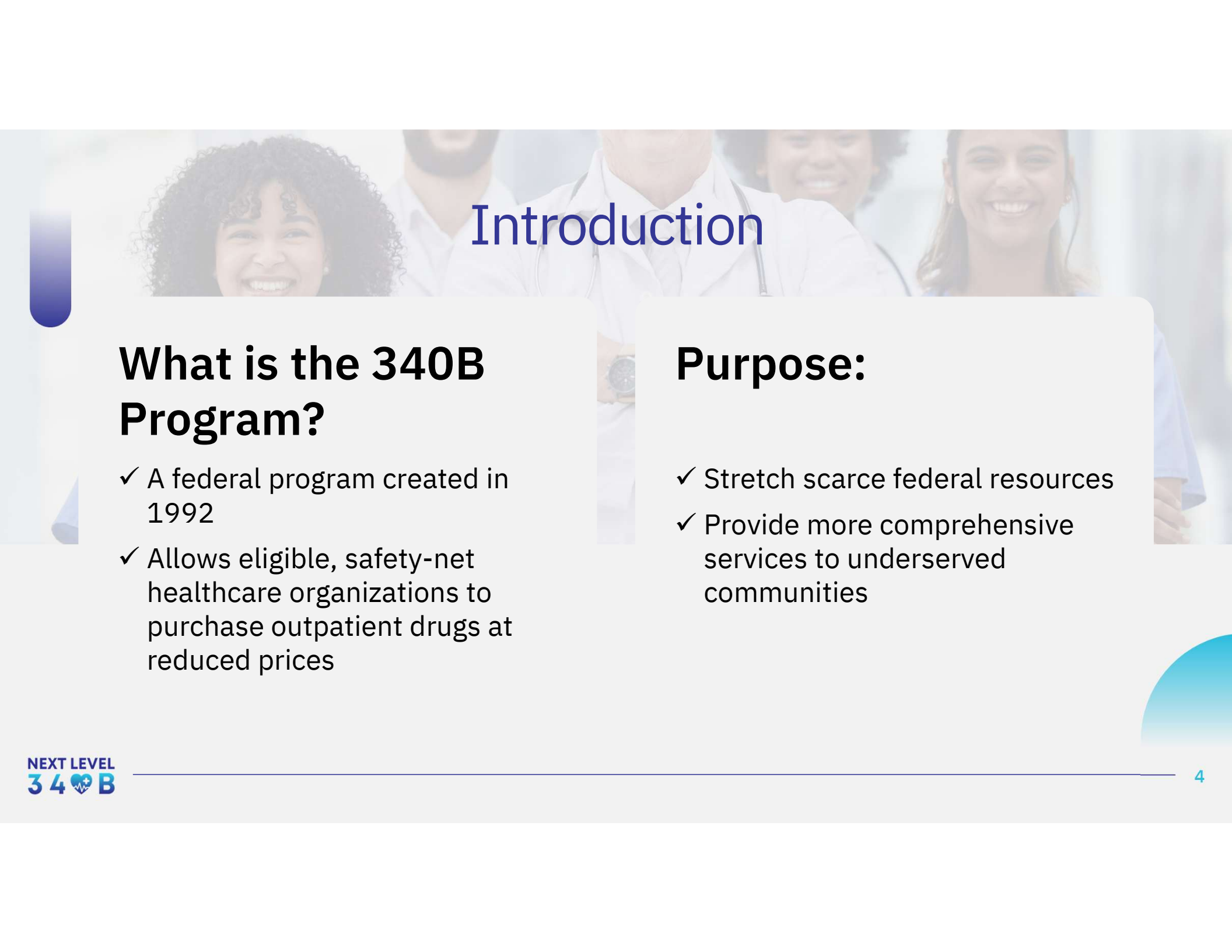
The 340B Crossroads

We are at a crossroads. One path leads to despair and hopelessness. The other to total extinction.

——— *Woody Allen (1980)*

But unlike Allen's satire, **340B** still has a real upside. But things are different now, and they will continue to look different moving forward.





Introduction

What is the 340B Program?

- ✓ A federal program created in 1992
- ✓ Allows eligible, safety-net healthcare organizations to purchase outpatient drugs at reduced prices

Purpose:

- ✓ Stretch scarce federal resources
- ✓ Provide more comprehensive services to underserved communities

Company Benefit



Patient Care

- ✓ Expanded Services
- ✓ Sustained Services
- ✓ The Three Pillars of Healthcare
 - Quality
 - Accessibility
 - Affordability



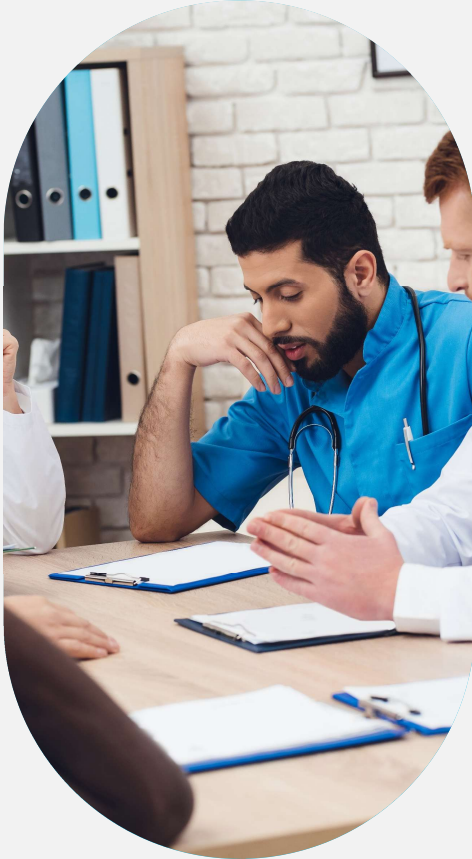
Strategic Planning

- ✓ Employee Benefits
- ✓ Community Partnerships
- ✓ Systems Integration



Financial

- ✓ Uncompensated Care
- ✓ Fund Operations
- ✓ Reduced ED visits and readmissions



Company Benefit

The purpose of business is to solve problems for people—profitably.

———— *Peter Drucker*

The stated purpose of **340B** is not just to pass down savings to patients in the sole form of reduced cost of drugs. In order to “Stretch scarce federal resources...” and “provide more comprehensive services..”, you need money. Unprofitable businesses **cannot** accomplish either.

Nonprofit ≠ No Profit

Compliance



Key Risks

- ✓ Duplicate Discount
- ✓ Diversion
- ✓ Policies
- ✓ OPAIS Accuracy



Recent Trend

- ✓ Increase in HRSA and manufacturer audits
- ✓ Growing focus on transparency and internal controls



Evaluating Recent HRSA Data

- ✓ Approximately 200 audits annually
- ✓ >80% of audits were on hospitals (41% CAH, 35% DSH, 5% PEDS/SCH)
- ✓ 52% had incorrect 340B OPAIS data
- ✓ 10% found duplicate discount
- ✓ 7% identified diversion
- ✓ 23% required manufacturer repayments
- ✓ 11% resulted in termination of a parent, child, or contract pharmacy location

Chaos in the Courts



Dozens of drug manufacturers have limited or refused 340B pricing at contract pharmacies, citing overreach and data transparency concerns.



Missouri (July 2025): Federal judge upheld state law requiring pharma to honor contract pharmacy discounts.



Arkansas: Supreme Court declined to hear PhRMA's appeal, letting stand a law protecting 340B access.



New Jersey, DC Circuit: Mixed rulings regarding HRSA enforcement authority.



Manufacturers (e.g., Sanofi, Novartis, AstraZeneca) continue appealing unfavorable rulings.



Patchwork rulings are creating compliance confusion and exposing covered entities to risk.

Chaos in Congress



Sen. Bill Cassidy's Report (April 2025): Criticized lack of transparency, called for:

- ✓ Mandatory reporting on use of 340B savings
- ✓ Limits on contract pharmacy relationships
- ✓ Program restructuring legislation



House Energy & Commerce Committee: Investigating PBM practices and 340B-related insurer impact.



Legislative Proposals:

- ✓ ASAP 340B Act: Federal override of conflicting state contract pharmacy laws
- ✓ Transparency & Reform Bills: Potential for bipartisan support with restrictions
- ✓ 340B PATIENTS ACT introduced in the Senate (July 2025)
 - Pharmaceutical Access To Invest in Essential, Needed Treatments & Support
 - Attempts to codify contract pharmacy access

No major federal law yet passed, but groundwork is being laid for reform packages in 2026. Most expect major reform.

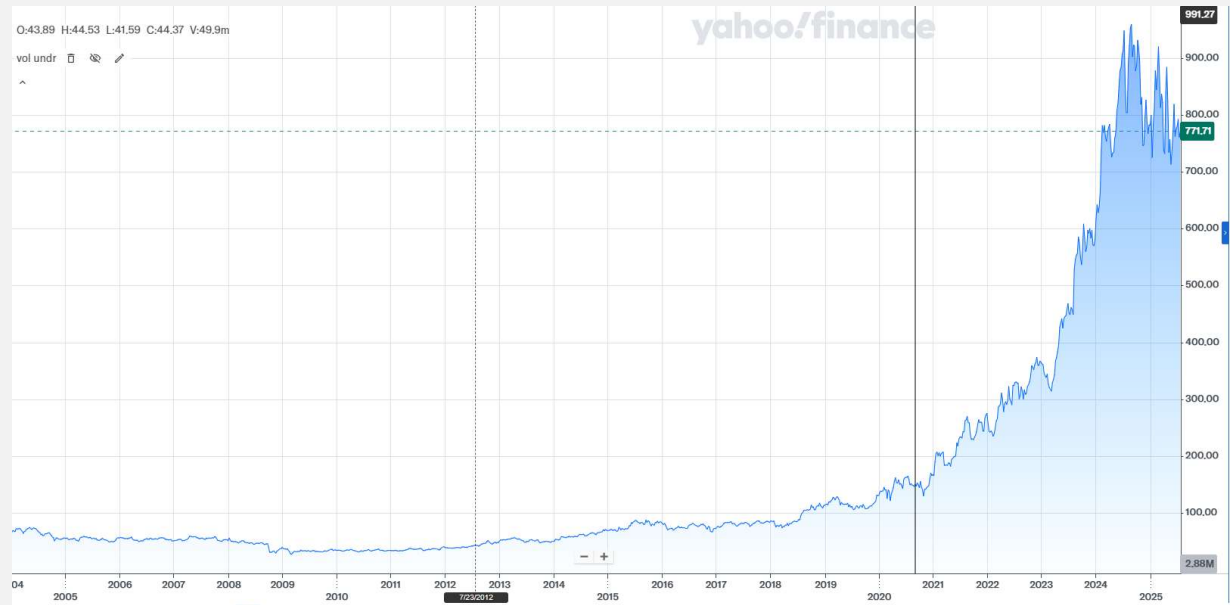
Manufacturers' Claims

Financial

- ✓ 340B increases insurance cost
- ✓ 4% or ~\$5B/year
- ✓ Provider Markup
- ✓ ~600%+ above cost
- ✓ 340B Program Growth
- ✓ 10% of their revenue or ~\$65B/year

Non-Financial

- ✓ Lack of oversight
- ✓ HRSA lacks authority
- ✓ Insufficient transparency
- ✓ No proof of compliance
- ✓ Inappropriate use of funds
- ✓ What % goes to patients?
- ✓ Fraud and Abuse



Eli Lilly (LLY)

- ✓ Price of stock on day of 340B restrictions was \$140.29
- ✓ Over 500% increase seen

Carefully Placed Roadblocks

Dark Money Deceit and Lies

- In October 2024, Stand for Us PAC received \$3.8M from “an undisclosed donor” to oppose state laws that protected 340B.
 - Abbvie v. Tennessee & Abbvie v. Colorado
 - AstraZeneca v. Nebraska
 - PhRMA v. Arkansas
 - PhRMA + Novartis + Abbvie v. West Virginia
 - Johnson & Johnson v. HRSA (federal)
- In January 2025, an organization named Building America’s Future started running ads across several states with pro-340B laws , including Mississippi, asserting that 340B was using tax dollars to fund free healthcare for illegals and to subsidize gender transitions for kids.
 - Distorted legislative debates and misinformed voters.
- In West Virginia, \$400k was spent on a smear campaign using targeted political ads against one GOP state senator who had recently (within weeks) supported a state law to protect 340B in his state.
 - He lost the primary.



Carefully Placed Roadblocks



ESP claim submission
requirements



ESP Balance Disputes and Pricing
Restoration



Limited Distribution



Redefinition of Terms (Confusion,
Obfuscation, & Gaslighting)



Fragmentation & Cognitive
Overload

Issues on the Horizon

- ✓ Planned for late 2025/early 2026
- ✓ Focused on Medicare Part B
- ✓ Results to be used in consideration of potential 2027 Medicare payment cuts on administered medications

Drug Acquisition Cost Survey



- ✓ Originated in the IRA of 2022
- ✓ First 10 negotiated drugs are set to go live with MFP on January 1, 2026
- ✓ Huge impact is likely!

Maximum Fair Price (MFP)



Rebate Model

- ✓ HRSA has opened the door
- ✓ Change in 340B Oversight?
- ✓ Upfront WAC, then wait on rebate
- ✓ Nuclear Option

Maximum Fair Price

Government-negotiated price that Medicare will pay for certain high cost drugs

Goal: Reduce Medicare drug spending and out-of-pocket costs

Time Line

2026

First 10 drugs. Only applicable to Part D

- Eliquis, Xarelto, Jardiance, Insulins, Farxiga, Entresto, Stelara, Enbrel, Januvia

2027

Adds 15 more drugs. Only applicable to Part D

- Currently in negotiations

2028

Adds 15 more drugs. Part B and part D

2029+

Adds up to 20 new drugs annually

You are not ready

Maximum Fair Price

Drug Name	Current Reimbursement/Unit (Estimated)	2026 MFP	Discount
Januvia	\$22.92	\$3.91	82.94%
Fiasp / NovoLog / Insulins	\$44.99	\$8.96	80.08%
Farxiga	\$23.29	\$6.05	74.02%
Enbrel	\$2,220.55	\$583.54	73.72%
Jardiance	\$24.44	\$6.79	72.22%
Stelara	\$33,411.92	\$8,979.65	73.12%
Xarelto	\$22.78	\$6.88	69.80%
Eliquis	\$11.89	\$4.15	65.10%
Entresto	\$13.76	\$5.23	61.99%
Imbruvica	\$702.49	\$353.94	49.62%

Maximum Fair Price

Drug Name	Current Reimbursement/Unit (Estimated)	2026 MFP	Reduction in Revenue
Januvia	\$22.92	\$3.91	82.94%
Fiasp / NovoLog / Insulins	\$44.99	\$8.96	80.08%
Farxiga	\$23.29	\$6.05	74.02%
Enbrel	\$2,220.55	\$583.54	73.72%
Jardiance	\$24.44	\$6.79	72.22%
Stelara	\$33,411.92	\$8,979.65	73.12%
Xarelto	\$22.78	\$6.88	69.80%
Eliquis	\$11.89	\$4.15	65.10%
Entresto	\$13.76	\$5.23	61.99%
Imbruvica	\$702.49	\$353.94	49.62%

Maximum Fair Price

- **You are not ready.**
 - Nobody is.
 - No working solution at present
 - Success requires teamwork between manufacturers, 340B entities, and a technology company that understands the complexity (consultants, PBMs, TPAs, etc.)
- **BUT**
 - Progress is being made on a solution
 - 2 in pilot stage. 1 showing promise
 - Some manufacturers are coming to the table
- **More than revenue reduction. Redefining the process**
 - “Duplicate Discount” is the battlefield
 - Solutions at Present
 - Give up 340B on these drugs completely
 - Take a reduced payment AND ensure PBMs don’t get a rebate under the redefined understanding of the phrase “duplicate discount”



Maximum Fair Price Predictions



Manufacturers will reinterpret 340B pricing obligations in light of the IRA.



HRSA will not take on responsibility for MFP-340B interaction oversight.



CEs dispensing MFP drugs will see their spread shrink or disappear.



A rebate model will become acceptable in the eyes of CMS and HRSA.



Commercial payers will attempt to adopt MFP-like reimbursements, leveraging MFP pricing as a benchmark.



A key stakeholder agnostic clearing house will become the gold standard for both compliance and MFP.



New codification of 340B for future clarity and survivability will occur

Rebate Model Pilot

1

Timeline

1. Launched August 1, 2025
2. Manufacturer application submission due by September 15, 2025
3. HRSA approvals by October 15, 2025
4. Go-live date of January 1, 2026

2

Important Information

1. Limited to the 10 MFP drugs, for now
2. 45-day window from dispense date to submission
3. 10-day limit for rebate payment post-submission
4. More information to come

3

Concerns

1. Frontloaded costs
2. Establishing precedent
3. Voluntary for manufacturers, required for 340B CEs
4. Expect rebate denials to become an issue



Stay in the know

Sources:

- 340B Health
- 340B Report
- Conferences
- Network with other 340B hospitals
- American Hospital Association
- Mississippi Hospital Association
- National Association of Community Health Centers (NACHC)





Dead End or Defining Moment?

This is a defining moment for 340B!

- We are at a pivot point—a crossroads. How do you know which way to go?
- Choose to follow the path that bring clarity, not just comfort.
- When the wind changes, be prepared to adjust the sails.
- Change is easier when it is expected and anticipated.
- If we can expect change, then we can influence change.

"Those who get ahead of change are best positioned to reshape it for good. Stay nimble."

Contact information

Any Questions?



CONTACT

Michael Summers MHSA, 340B
ACE, Next Level 340B



EMAIL

mike@nextlevel340b.com
msummers.healthcare@yahoo.com



PHONE

662-582-5610



WEBSITE

www.nextlevel340b.com

