



Navigating 340B Updates and Strategies

April 2025



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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.

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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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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 UICX survey NPS®

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Agenda

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



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Initial Thoughts

How to Move Forward

- How are you planning for the future with uncertainty?
- 2023 340B purchasing – 9.2% of total purchasing in US – \$66.3B
- 2023 Top 5 manufacturers by revenue spent \$75.1B in marketing
- What are you doing to support advocacy at the state and federal levels?
- What are you doing to think differently with so many potential changes in 340B?
- Are you utilizing data to assess potential changes in provider-based, 340B and pharmacy?
- How are you preparing for increase in costs due to tariffs and other factors?
- Do you have the resources that you need?

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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

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Eligibility

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

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HRSA Audits

- Introductory calls have become more informational - expectation is to provide details on program operations
- Issues currently undergoing challenges
 - Scope of patient definition (especially related to referrals and the need for notes back)
 - Diagnostic testing as the qualifying patient encounter
 - MTMs - No issue when written from an eligible location, findings when prescriptions originate from a non-PBB clinic/location
- Trends in duplicate discount findings
 - Entity and/or site listed as carving in but not purchasing drugs on 340B accounts
 - Out of state Medicaid numbers not listed on MEF
 - Billing numbers for a child site not listed on MEF

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340B Program Strategy



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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

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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

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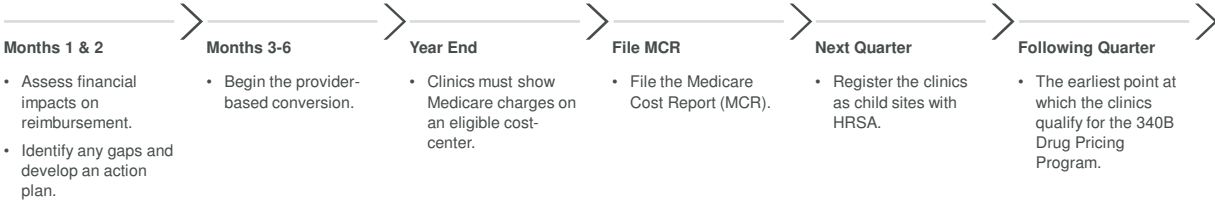
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Outline Provider-Based & 340B Timeline

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

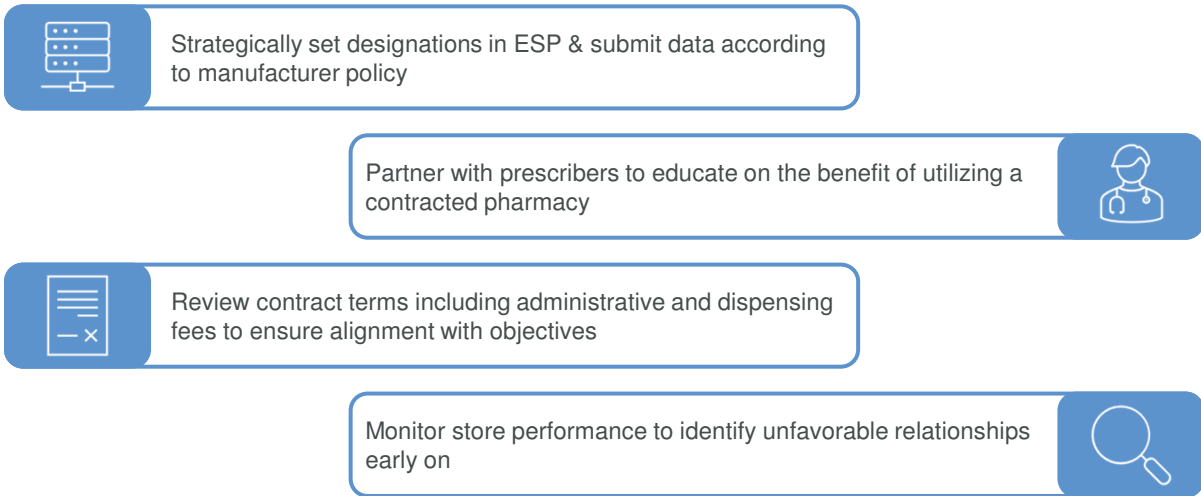
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Contract Pharmacies Maximizing Your Network



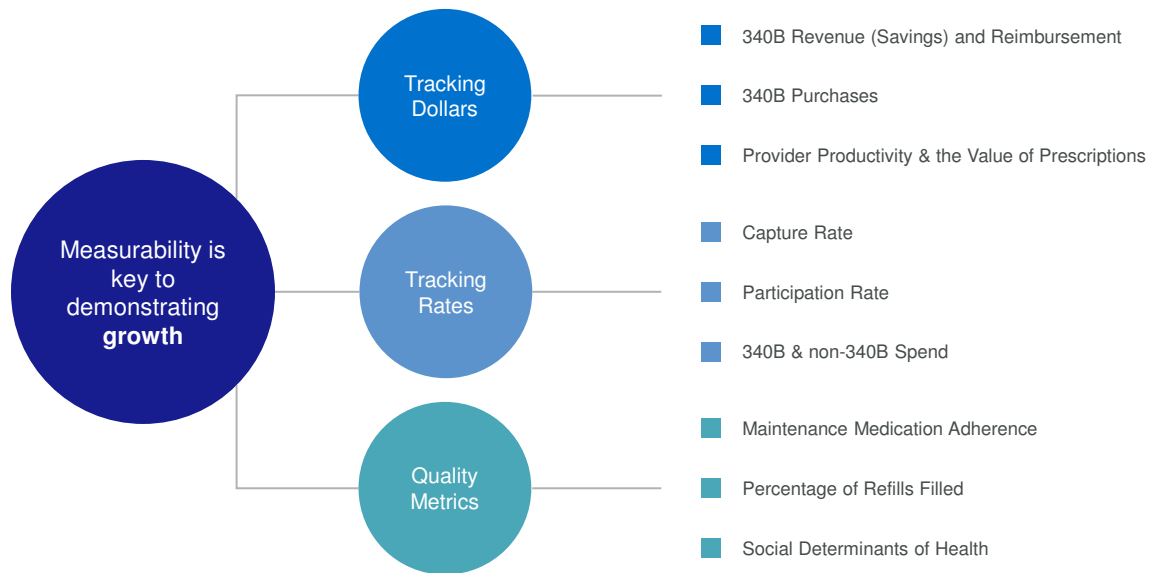
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340B KPIs



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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

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State of Arkansas

95th General Assembly

Regular Session, 2025

By: Senators J. Dismang, Irvin

By: Representatives Eubanks, Wardlaw

As Enrolled: 5/30/25

A Bill

SENATE BILL 58

For An Act To Be Entitled

AN ACT TO REMOVE THE PROHIBITION ON NONPROFIT, TAX EXEMPT, OR GOVERNMENTALLY-FUNDED HOSPITALS HOLDING A LICENSED PHARMACY PERMIT FOR THE SALE AT RETAIL OF DRUGS; AND FOR OTHER PURPOSES.

Subtitle

TO REMOVE THE PROHIBITION ON NONPROFIT, TAX EXEMPT, OR GOVERNMENTALLY-FUNDED HOSPITALS HOLDING A LICENSED PHARMACY PERMIT FOR THE SALE AT RETAIL OF DRUGS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code § 17-92-101, concerning definitions regarding pharmacists and pharmacies, is amended to add an additional subdivision to read as follows:

(27) "Hospital campus" means the main buildings of the hospital, including areas and structures that are not strictly contiguous to the main building, but excluding parking lots and other parcels dedicated to the public's use.

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Entity-Owned Pharmacy

The Benefit of Internalizing Your Prescriptions

The Patient Care Benefit

Continuity & total ownership of care

Patient convenience

Integration of pharmacy with the care team

Financial Upsides

Avoid manufacturer restrictions on contract pharmacy arrangements

Additional revenue-generating service line

Potential for additional reimbursable services

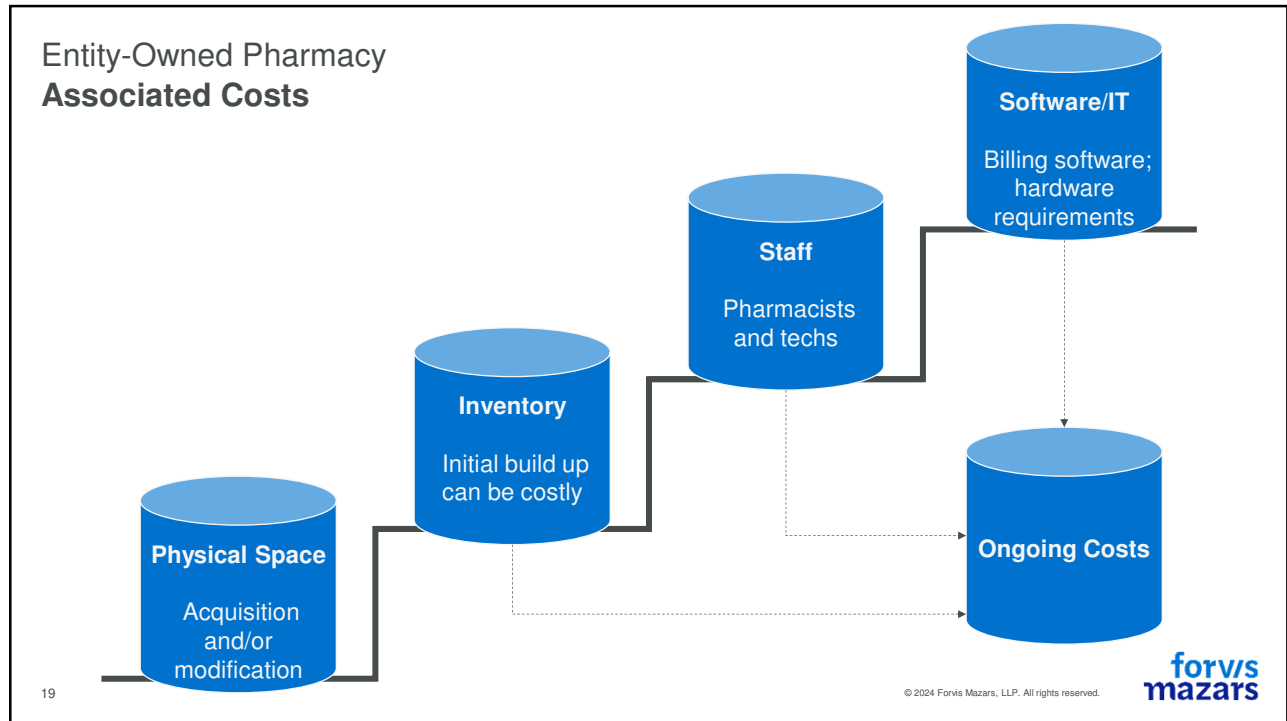
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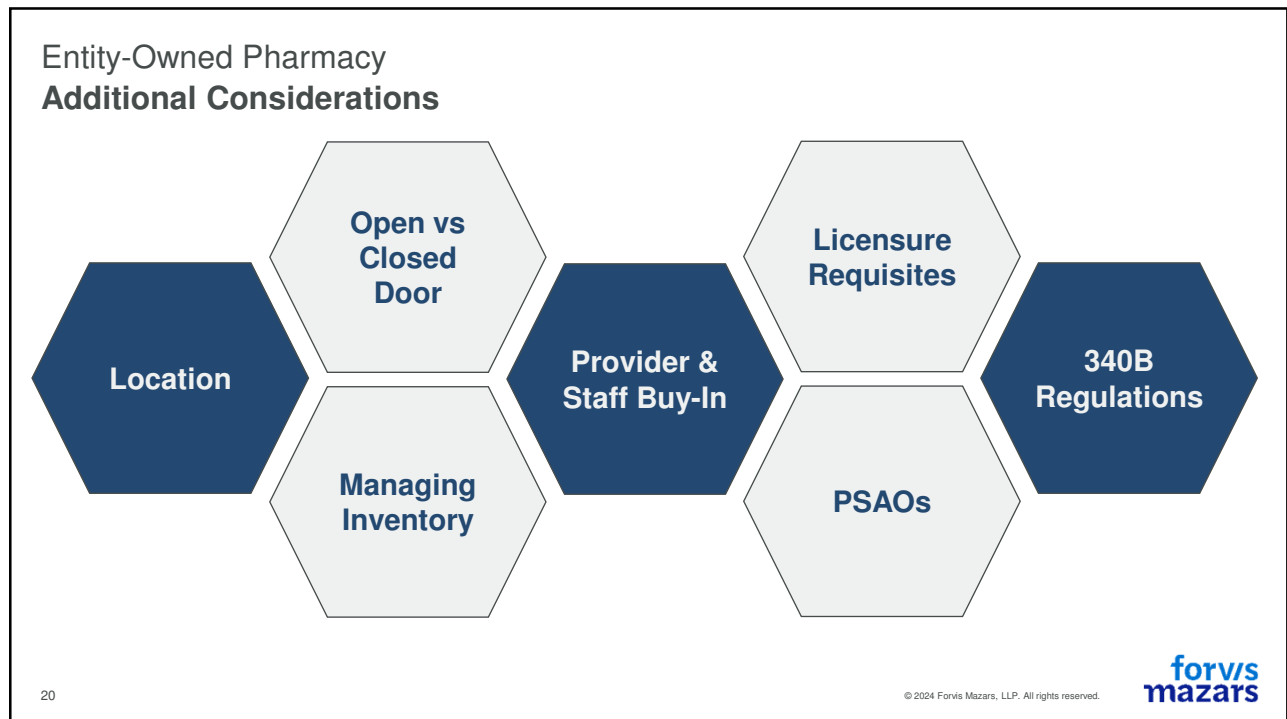
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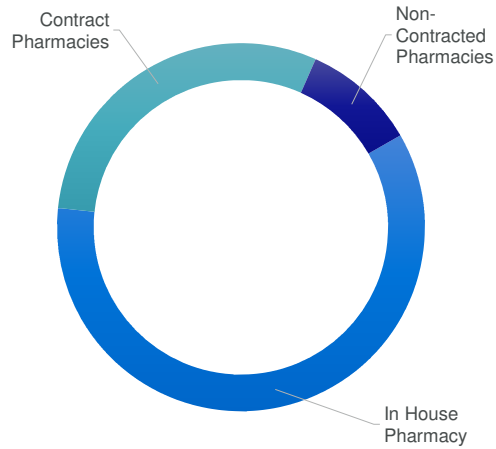
Key Performance Indicator Capture Rate

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%



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Enhanced Community Care Models Integration of Pharmacy Services

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

- Pharmacist Led Services
- Collaborative practice agreements
- Referral arrangements
- Documentation



Considerations

- Comprehensive tracking mechanism
- Pharmacist as a qualifying provider
- Pharmacist embedded in a qualifying location
 - 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 & procedures
- Differences in billing practices by payor
- Communication gaps between providers, patients, & pharmacists

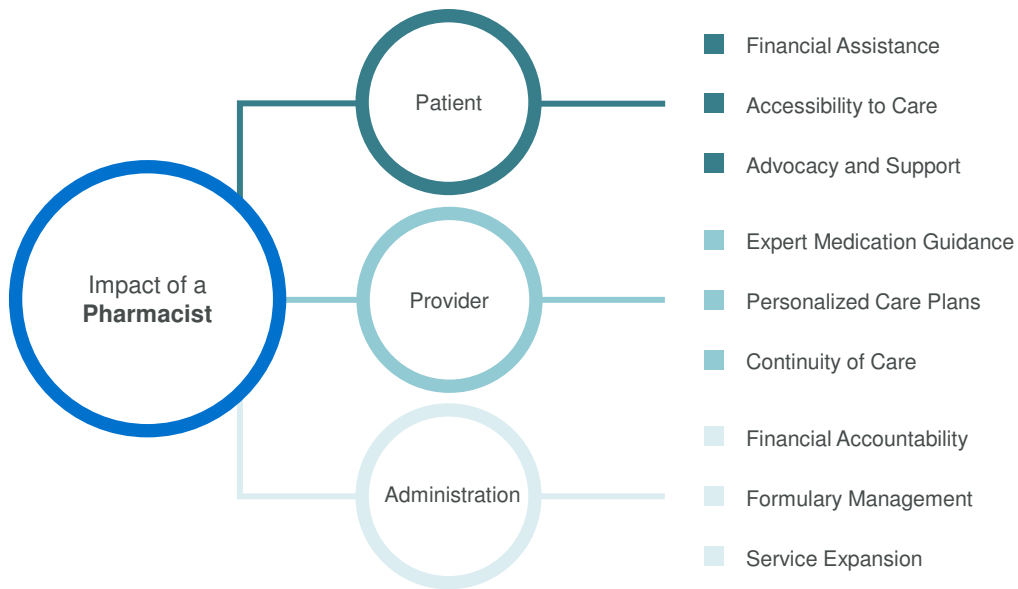
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Enhanced Community Care Models Integration of Pharmacy Services



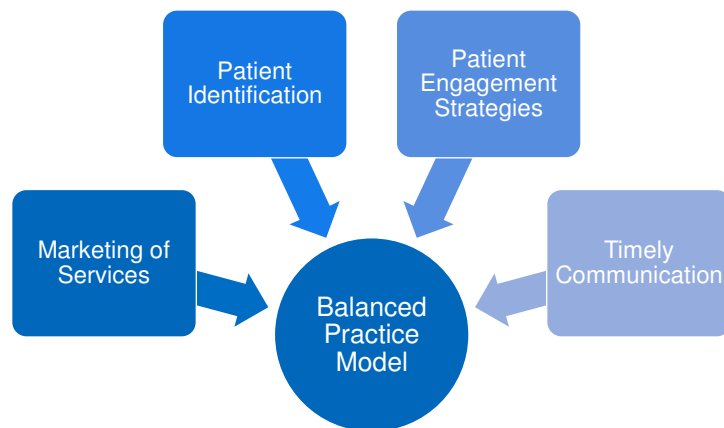
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Enhanced Community Care Models Integration of Pharmacy Services



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Marketing of Services

- Staff communication
- Promotional materials
- Referral arrangements

Patient Identification

- Methodology
- Documentation
- Address Provider Gaps

Patient Engagement

- Education on Service Offerings
- Access to Care

Communication

- Regular meeting intervals
- Open lines of communication
- Quality Improvement

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Enhanced Community Care Models Integration of Pharmacy Services

Is your team positioned to succeed?

Core Elements

- Dedicated workspace
- Ensure access to essential tools
 - Electronic Health Record (EHR)
 - Scheduling platform
- Utilize staff strengths and certifications
- Identify and communicate expectations

Long-Term

- Prepare meeting agendas
- Outline Referral Process
- Establish Key Performance Indicators to monitor collaboration
- Implement Quality Improvement initiatives
- Develop Collaborative Practice Agreements
- Expand preventative services



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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



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Artificial Intelligence Utilization in Pharmacy Practice

Transforming the Industry



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Inventory Optimization
Diversion Monitoring
Medication Management
Telepharmacy
Patient Triage
Diagnostic Image Review
New Drug Development

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Manufacturer Barriers



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Contract Pharmacy Addressing Manufacturer Restrictions

Since September 2020, manufacturers have taken steps to unlawfully block and limit access to 340B savings.

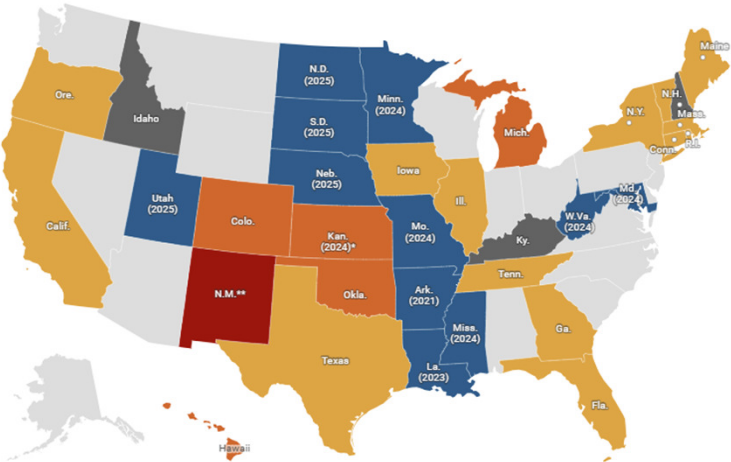


Source: 340B Health
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- 36 Manufacturers with contract pharmacy limitations
- 8 States with legislation protecting contract pharmacy relationships
- \$1B Savings lost to only 5 manufacturers in 2021

Legislative Update Addressing Manufacturer Restrictions

2025 State Legislation Tracker: Contract Pharmacy Access Bills and Laws
■ Law passed ■ Bill introduced in 2025 ■ Bill cleared first legislative chamber ■ Bill with state governor ■ Bill died



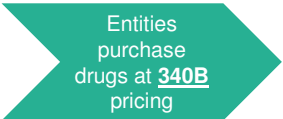
BREAKING NEWS
Supreme Court Declines to Hear PhRMA's Challenge to Arkansas' Landmark 340B Contract Pharmacy Access Law

Current Concerns The Rebate Model

4 manufacturers (J&J, BMS, Eli Lilly & Sanofi) have attempted to implement a rebate model in which 340B savings are recognized on the back-end.

HRSA/HHS strongly oppose such models and have threatened termination from Federal Health Insurance Programs if models are implemented. The current administration has indicated that they will uphold this stance.

Current State



Proposed State



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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 →

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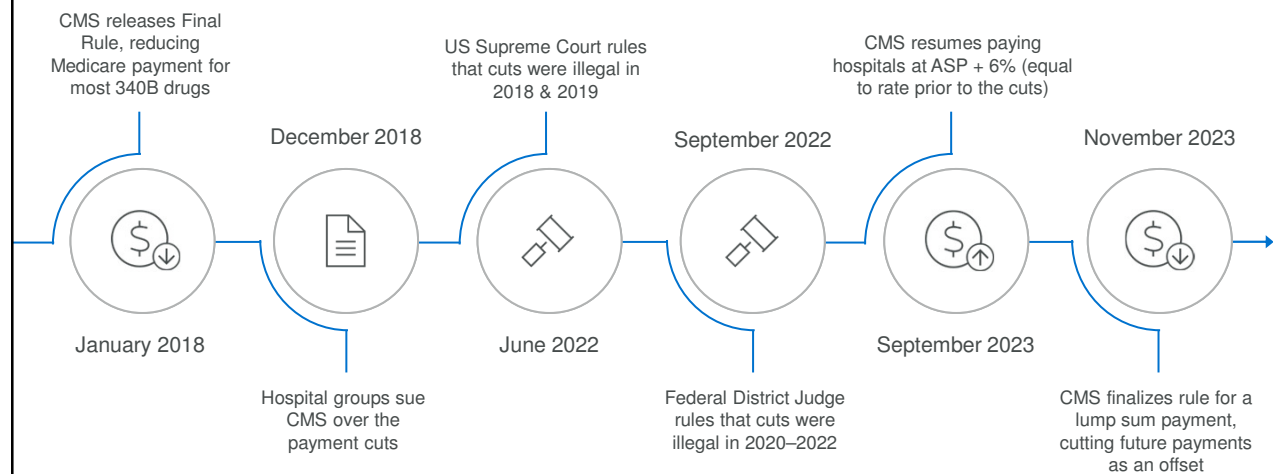
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340B Program Outlook



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OPPS Remedy Timeline



However, the final rule did not address Medicare Advantage plans.

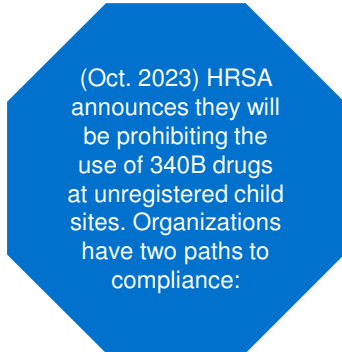
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Unregistered Child Sites



Hospitals with sites already on their MCR but not on OPAIS, must register the sites on OPAIS during the next registration window (January 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. 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.

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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

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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

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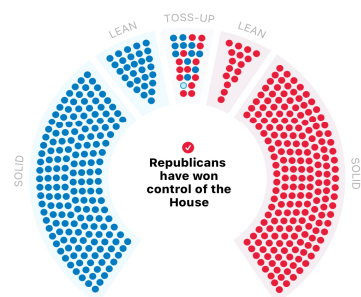
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2024 Election – Congress



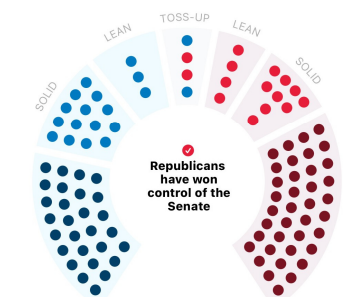
The Republicans have held the
House of Representatives....

...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

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Source: Cook Political Report

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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.



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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	340B	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

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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

	Federal	State
Legislative	H.R. 7635: 340B PATIENTS Act SUSTAIN 340B Act H.R. 8574: 340B ACCESS Act	Contract Pharmacy Laws Passed MN, MO, KS, AR, MS, LA, MD, WV
Litigation	AHA v. Becerra <i>Supreme Court of the U.S.</i> Novartis v. Carole Johnson <i>Court of Appeals for D.C. Circuit</i> Sanofi-Aventis U.S. v. HHS et al. <i>U.S. Court of Appeals for the Third Circuit</i>	Contract Pharmacy Laws Upheld AR, MD, LA Contract Pharmacy Laws Challenged LA, MS, WV, MN, MO, KS

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Source: <https://essentialhospitals.org/states-pass-340b-contract-pharmacy-nondiscrimination-legislation>

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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



- Jerry Morgan (R-Kansas)
- Tammy Baldwin (D-Wisconsin)
- Shelley Capito (R-West Virginia)
- Tim Kaine (D-Virginia)
- Markwayne Mullin (R-Oklahoma)
- John Hickenlooper (D-Colorado)

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Site Neutrality Likely Expanded



Policies expanding site-neutral payments & care delivery in lower cost settings are supported by think tanks aligned with President Trump.



BILL CASSIDY, M.D.
U.S. Senator for Louisiana



MAGGIE HASSAN
UNITED STATES SENATOR FOR NEW HAMPSHIRE

LOWERING HEALTH COSTS FOR SENIORS FRAMEWORK

U.S. Senators Bill Cassidy, M.D. and Maggie Hassan are working together on the below policy options for site-neutral payment reform. This paper explores policy options for payment reform that would reduce health care costs for patients and taxpayers, improve the financial stability of Medicare, reduce provider consolidation, and provide assistance to hospitals serving rural and high-needs communities.

INTRODUCTION

The high cost of health care in the United States is a significant burden on families and taxpayers. Three in four adults worry about their ability to afford unexpected medical bills for themselves or their family.¹

As hospitals expand their ownership of physician practices and outpatient care facilities, patients are increasingly paying high hospital prices in these previously low-cost settings. Under the Medicare program, taxpayers and patients now share the cost of hospital “facility fees” – hundreds of dollars in additional fees which are now being charged when a patient gets basic care, such as a steroid injection or an allergy test. Patients with private insurance are also facing hundreds of dollars in facility fees for basic care, without ever setting foot in a hospital.

Potential Policy Actions

- Legislation:

 - Repeal “Section 603” HOPD Exemptions
 - Site Neutrality Across HOPD, ASC, & MD Office
 - Off-Campus HOPD Billing Identifier
 - Funding to Support Rural/Safety Net Hospitals
- Administrative Action:

 - Phase Out Inpatient Only List
 - Expand ASC Covered Procedure List



Sources:
1) <https://www.cassidy.senate.gov/wp-content/uploads/2024/10/Site-Neutral-Policy-Framework-Final.pdf>

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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

Manufacturers

- Amgen
- Eli Lilly



Advocacy Action Steps



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Questions?



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