



340B Drug Pricing Program Update

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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.

Every industry is different, and we put a strong focus on specific industry experience and knowledge of your complex and evolving environment. We provide a range of audit and assurance, tax, advisory and consulting services to help your business by bringing together experienced professionals from all over the globe who understand local contexts and cultures.

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

forvismazars.com/global

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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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ClearlyRated - NPS® 101 for Accounting Firms.

Performance Improvement Pharmacy & Clinic Services

340B Compliance

Accurate, complete, and auditable records are essential for providers to maintain compliance and identify the program's key risks. Forvis Mazars performs independent external 340B assessments for covered entities throughout the country.

340B Program Development & Optimization

We help with many different aspects, including registration assistance, policy and procedure development, child site evaluation, expansion of contract pharmacy arrangements to increase savings, and split-billing software implementation assistance and operational improvements.

340B Co-Sourcing

Forvis Mazars can assist you in finding ways to support bandwidth constraints in your 340B program. The Forvis Mazars team has significant experience assisting organizations by providing services to expand teams to help meet 340B organizational goals.

Provider-Based Billing

We can help hospitals with provider-based billing strategies and help meet CMS requirements and operationalize provider-based clinics.

Pharmacy Expansion

The expansion of pharmacy services is critical for an organization to increase its financial sustainability. Forvis Mazars can assist organizations with identifying expansion opportunities and exploring associated risks and benefits.

Pharmacy Structure

Pharmacy charge structure and integrity are more critical than ever in the accelerated healthcare environment as transparency continues to be of the utmost focus. Up-to-date crosswalks, formularies, and modifiers are critical to help improve reimbursement and maintain compliance.

Opioid Assistance

The opioid epidemic has been an uphill battle for healthcare providers, which must have access to information to understand the risks associated with all aspects of treating patients with opioids and assisting those with opioid dependency and overuse.





340B in Washington



340B Program Strategy

Group Discussion



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?
- What about the One Big Beautiful Bill?
- Do you have the resources that you need?

340B In Washington





Senate HELP Committee Chair Cassidy plans to introduce bill to mitigate “misuse.”



Senate HELP Committee Chair Calls for 340B Reforms, Releases Findings of Yearslong Probe

The leader of a key U.S. Senate committee overseeing the 340B program calls for greater transparency and “ensuring that the revenue created from the program is used for its intended purpose” from his yearslong probe.

U.S. Sen. Bill Cassidy, a leading 340B program critic who chairs the Senate HELP Committee, announced the findings of his yearslong probe into the program.



Cassidy Staffer, ASAP 340B Head Call for 340B Program Reforms, Comment on Proposed Shift to CMS

A key health policy staffer for U.S. Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Bill Cassidy (R-La.) recently joined 340B critics in calling for major program reforms based on the senator’s investigation into the pricing program— noting how they could align with drugmakers’ proposed 340B rebate models and a potential U.S. Department of Health and Human Services (HHS) shakeup.

Sources:

- 1) <https://340breport.com/senate-help-committee-chair-cassidy-calls-for-federal-340b-reforms-releases-findings-of-yearslong-congressional-probe/>
- 2) <https://340breport.com/cassidy-staffer-asap-340b-head-call-for-340b-program-reforms-comment-on-proposed-shift-to-cms/>



340B Legislation & Litigation

- Legal and admin action related to rebate models bears watching
- The administration is likely to reduce Part B payments for 340B drugs...again.

	Legislation	Admin Action	Litigation
Federal	<p>Reintroduced from 118th Congress?</p> <p>H.R. 7635: 340B PATIENTS Act</p> <p>SUSTAIN 340B Act</p> <p>H.R. 8574: 340B ACCESS Act</p>	<p>HRSA to Produce Rebate Model Guidance</p>	<p>Sanofi-Aventis U.S. v. HHS</p> <p>U.S. District Court for D.C.</p>
State	<p>Hospital Contract Pharmacy Laws Passed</p> <p>HI, OR, UT, CO, ND, SD, NE, OK, MN, MO, AR, LA, MS, TN*, MD, WV, VT, ME, RI</p>		<p>Contract Pharmacy Laws Upheld</p> <p>AR, MD, LA</p> <p>Contract Pharmacy Laws Challenged</p> <p>LA, MS, WV, MN, MO, KS</p>

Current Congressional Bills



Bill Number	Bill Name	Bill Purpose	Bill Sponsors	Introduced	Senate	Status	Committee Assignments	Last Action
H.R. 44	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 bill would add facilities designated as Rural Emergency Hospitals as a 340B covered entity type.	Rep. Jack Bergman (R-MI) and Rep. Debbie Dingell (D-MI)	January 3, 2025	House	In Committee	Energy & Commerce	Referred to the House Committee on Energy and Commerce on 1/3/2025.
H.R. 2197	No 340B Savings for Transgender Care Act	The bill would bar providers from using 340B savings on "sex reassignment surgeries [and] hormone treatments furnished for the purpose of the gender alteration of a transgender individual."	Rep. Dusty Johnson (R-SD)	March 18, 2025	House	In Committee	Energy & Commerce	Referred to the House Committee on Energy and Commerce on 3/18/2025.
H. R. 3222	SMART Health Care Act	The bill would require 340B providers to charge patients the 340B price for covered drugs, "less any additional discounts or rebates received by the covered entity." It would also authorize Health and Human Services secretary to reduce Medicare reimbursement for those drugs to the 340B price, eliminating providers' ability to generate 340B savings on Medicare patients. Covered entities would have to publicly report the total amount paid by Medicare and the amount received by the covered entity for covered outpatient drugs.	Rep. Victoria Spartz (R-IN)	May 6, 2025	House	In Committee	Energy & Commerce, Ways and Means	Referred to the House Committees on Energy and Commerce and Ways and Means on 5/6/2025.
H.R. 4317	PBM Reform Act	The bill would ban "spread pricing" in Medicaid, set new requirements for PBMs under Medicare Part D; require semi-annual reporting on drug spending, rebates and formulary determinations; and direct CMS to define and enforce "reasonable and relevant" contract terms in Medicare Part D pharmacy contracts and enforce oversight on reported violations.	Rep. Earl "Buddy" Carter (R-GA)	July 10, 2025	House	In Committee	Energy & Commerce, Ways and Means, Education and Workforce	Referred to the House Committees on Energy and Commerce, Ways and Means and Labor and Workforce on 7/10/2025.

Source: 340B Report



Drug Pricing Executive Order

The EO potentially resurrects many of the prior Trump administration's drug pricing policies.

Excerpted Sections from Drug EO Impacting Providers

Sec. 4. Reducing the Prices of High-Cost Drugs for Seniors. Within 1 year the Secretary shall take steps to select for testing a payment model to obtain better value for high-cost prescription drugs covered by Medicare.

Sec. 5. Accounting for Acquisition Costs of Drugs in Medicare. Within 180 days publish a plan to conduct a survey to determine the hospital acquisition cost for covered outpatient drugs at HOPDs.

Sec. 7. Access to Life-Saving Medications. Within 90 days take action to ensure future grants are conditioned upon making insulin and injectable epinephrine available at or below the price paid under the 340B Program to low-income individuals.

Sec. 11. Reducing Costly Care for Seniors. Within 180 days evaluate and propose regulations to ensure that payment within Medicare is not encouraging a shift in drug administration volume away from less costly physician office settings.

Key Takeaways:

- **Sec. 5:** OPSS 340B Part B Separately Payable Drug Reduction
- **Sec. 7:** Requires FQHCs to provide insulin and epinephrine at or below 340B price to low-income individuals.
- **Sec. 11:** OPSS site-neutral payments for drug administration services.

Sources:

- 1) <https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/>



Current Concerns

The Rebate Model

5 manufacturers 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





Rebate Model Litigation

A HRSA proposed rule related to rebate models is currently under review.

Federal Judge Upholds HHS' Right to Pre-Approve 340B Rebates, Tosses Four of Five Drugmaker Lawsuits

A federal district judge has ruled that the law does not require agency approval of drug rebates, a blow to manufacturers' efforts to reform the drug pricing program.

In a May 15 [opinion](#), Judge D. Paul O. Walker of the District of Columbia rejected the lawsuit filed by Bristol-Myers Squibb (BMS), Novartis, and other drugmakers against the Health and Human Services' requirement of their 340B rebate approval.

HHS to Issue Guidance on 340B Rebates, IRA Interaction Within 30 Days

A national group representing 1,500-plus 340B hospitals and two of its members have filed to intervene in federal court cases targeting controversial 340B rebate proposals from Bristol-Myers Squibb (BMS), Eli Lilly, Novartis and Sanofi after previously doing so in Johnson & Johnson's (J&J) similar case.

340B Health joined UMass Memorial Medical Center (UMMC) and Genesis Healthcare System—340B hospitals based in Worcester, Mass. and Zanesville, Ohio, respectively—in filing motions to intervene in the four lawsuits on Feb. 5....

Sources:

- 1) <https://340breport.com/federal-judge-upholds-hhs-right-to-pre-approve-340b-rebates-tosses-four-of-five-drugmaker-lawsuits/>
- 2) <https://340breport.com/hhs-to-issue-guidance-on-340b-rebates-ira-interaction-within-30-days/>



OBBBA: Decreased Medicaid Enrollment

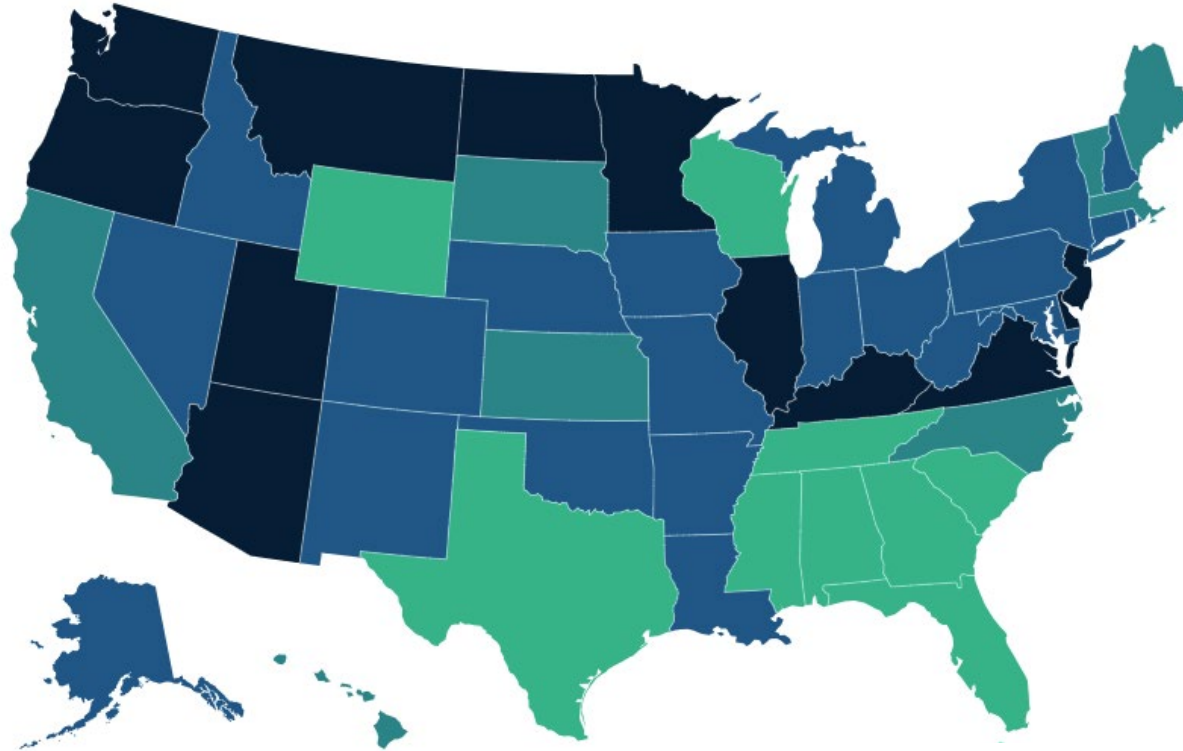
OBBBA will significantly reduce re-enrollment, which could reduce hospitals' DPP.

Figure 3

Estimated Medicaid Enrollment Loss in the House Reconciliation Bill, By State

As a % of baseline Medicaid enrollment in 2034

■ < 8% ■ 8%–12% ■ 12%–16% ■ ≥ 16%



Note: The provisions resulting in enrollment loss account for \$671 billion out of the \$793 billion in Medicaid spending reductions, including a proportional amount (\$59 billion) of the interaction effects. See Methods in "Allocating CBO's Estimates of Federal Medicaid Spending Reductions and Enrollment Loss Across the States: House Reconciliation Bill" for more details.

Source: KFF analysis of CBO estimates of the House Reconciliation Bill • [Get the data](#) • [Download PNG](#)

KFF

Unregistered Child Sites



(Oct. 2023) HRSA announces 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 (January 1–16)

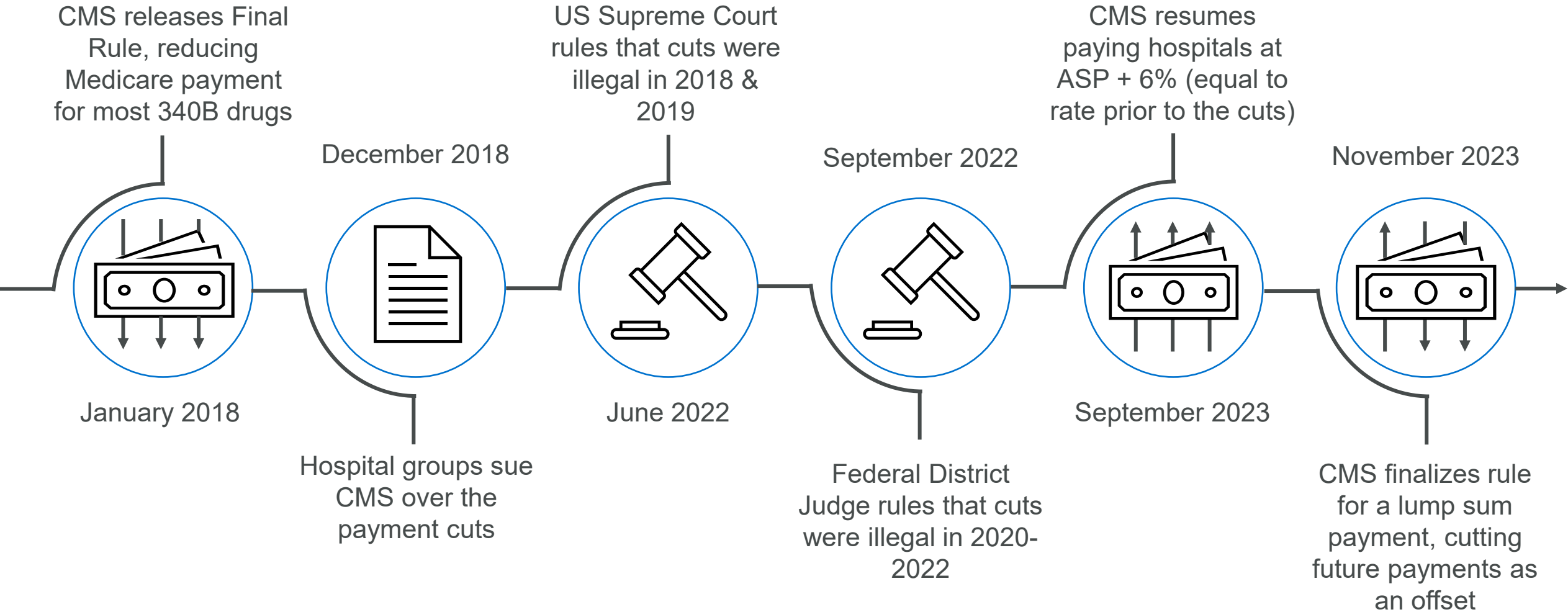
Hospitals with sites *not* on the MCR nor OPAIS must submit the following information to HRSA by January 25, 2024:

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 & health systems is currently being pursued against HRSA as it relates to this ruling.



OPPS Remedy Timeline



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



DSH Calculation: Section 1115 Waiver Days

HHS is appealing a lower court ruling vacating CMS' final rule excluding 1115 waiver days from the Medicare DSH calculation.



HHS Appeals Court Ruling That Blocked DSH Calculation Changes That Impact 340B Eligibility

The Biden Administration has asked a federal appeals court to reconsider a Texas judge's ruling that voided a Department of Health and Human Services (HHS) rule used to help calculate hospitals' 340B eligibility.


Attorneys representing HHS Secretary Xavier Becerra [notified](#) the U.S. District Court for the Northern Division of Texas' Fort Worth Division on Oct. 14 of the agency's appeal of District Judge Mark Pittman's Sept. 25 [judgment](#)—which declared HHS' October 2023 [Inpatient Prospective Payment Services \(IPPS\)](#) final rule “unlawful” and halted its enforcement.


The U.S. 5th Circuit Court of Appeals will now review the ruling in the case...



Site Neutrality Likely Expanded

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





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

340B Program Strategy





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

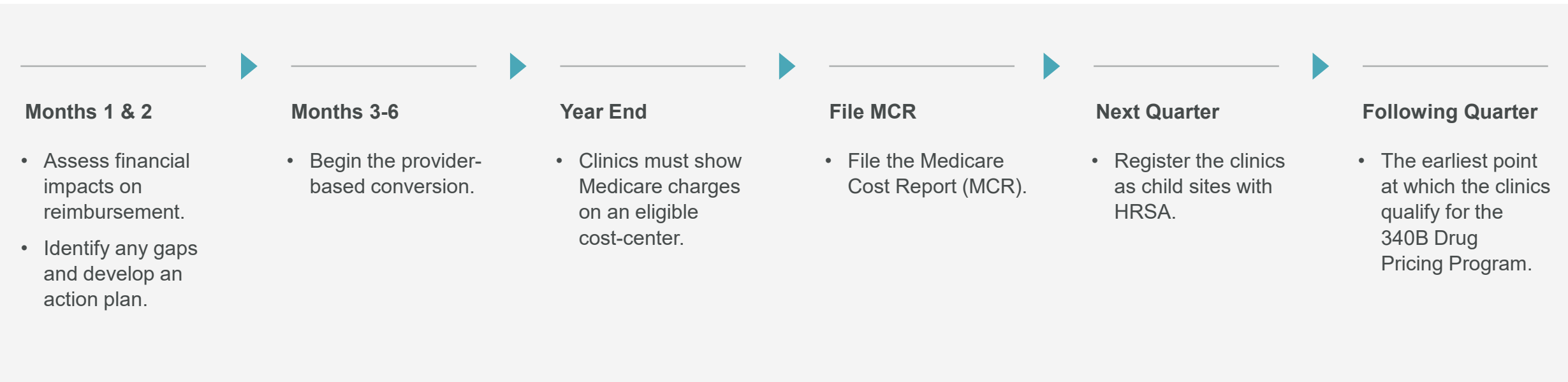
- Clinics must have naming associated with hospital
- Will need to update all collateral & signage
- Patient and staff education



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



340B Steering Committee

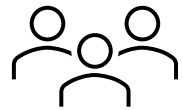
Program Oversight and Compliance

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

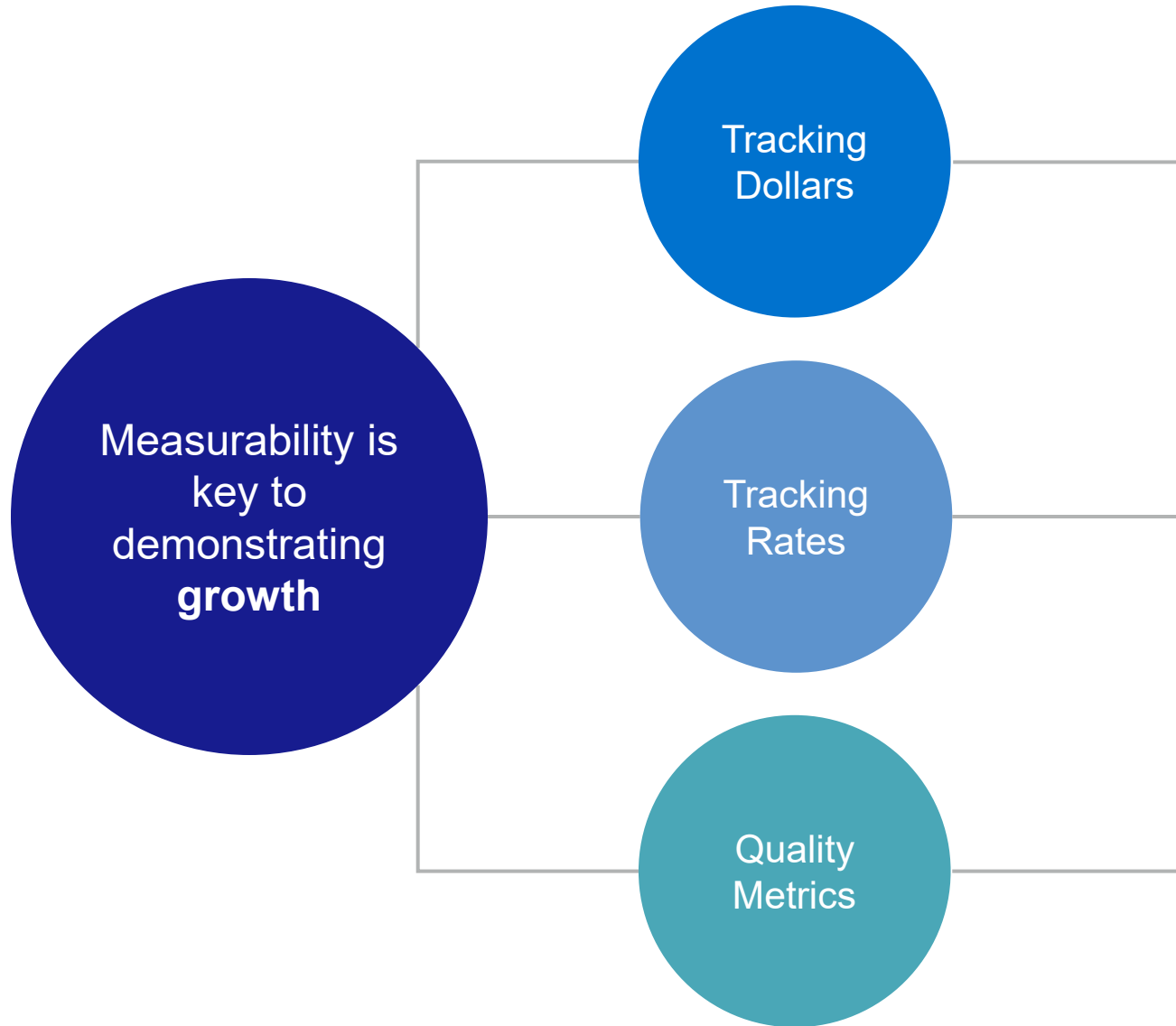
IT
Legal
Pharmacy
Patient Services
Compliance
Finance



Compliance

Policies and procedures
Conduct frequent mock audit procedures
Utilize independent external reviews
Medicaid BIN/PCN/GRPs
Eligible locations
Qualification parameters

340B KPIs



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



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



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.

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)





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

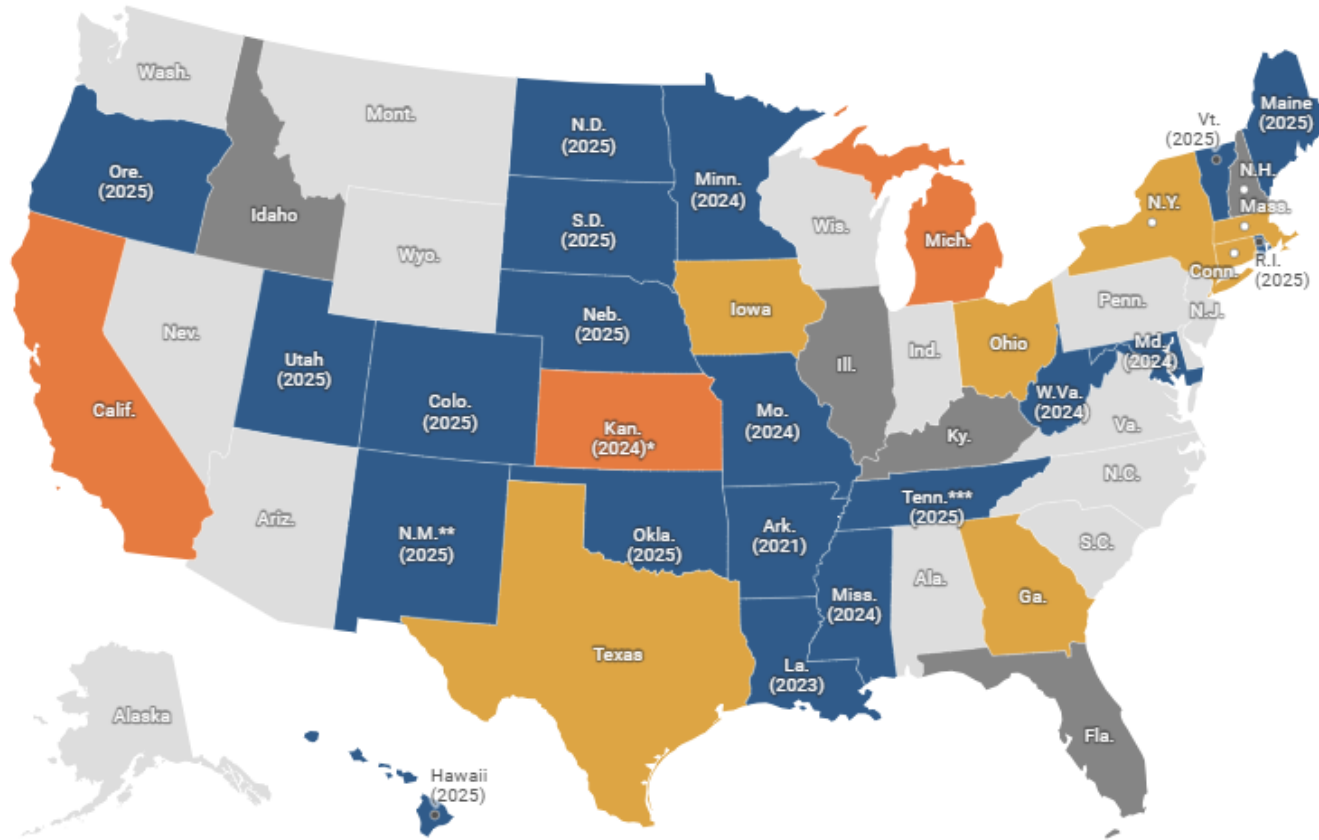
- May end up in Supreme Court if Appeals issue diverging opinions
- 2 courts sided with manufacturers
- 1 case pending



Contract Pharmacy Addressing Manufacturer Restrictions

340B REPORT 2025 State Legislation Tracker: Contract Pharmacy Access Bills and Laws

■ Law passed ■ Bill introduced ■ Bill cleared first chamber ■ Bill with state governor ■ Bill died or 2025 session over



* Kansas lawmakers introduced a new bill in 2025 amid concerns over the 2024 contract pharmacy law's enforceability.

** New Mexico's law only applies to community health centers.

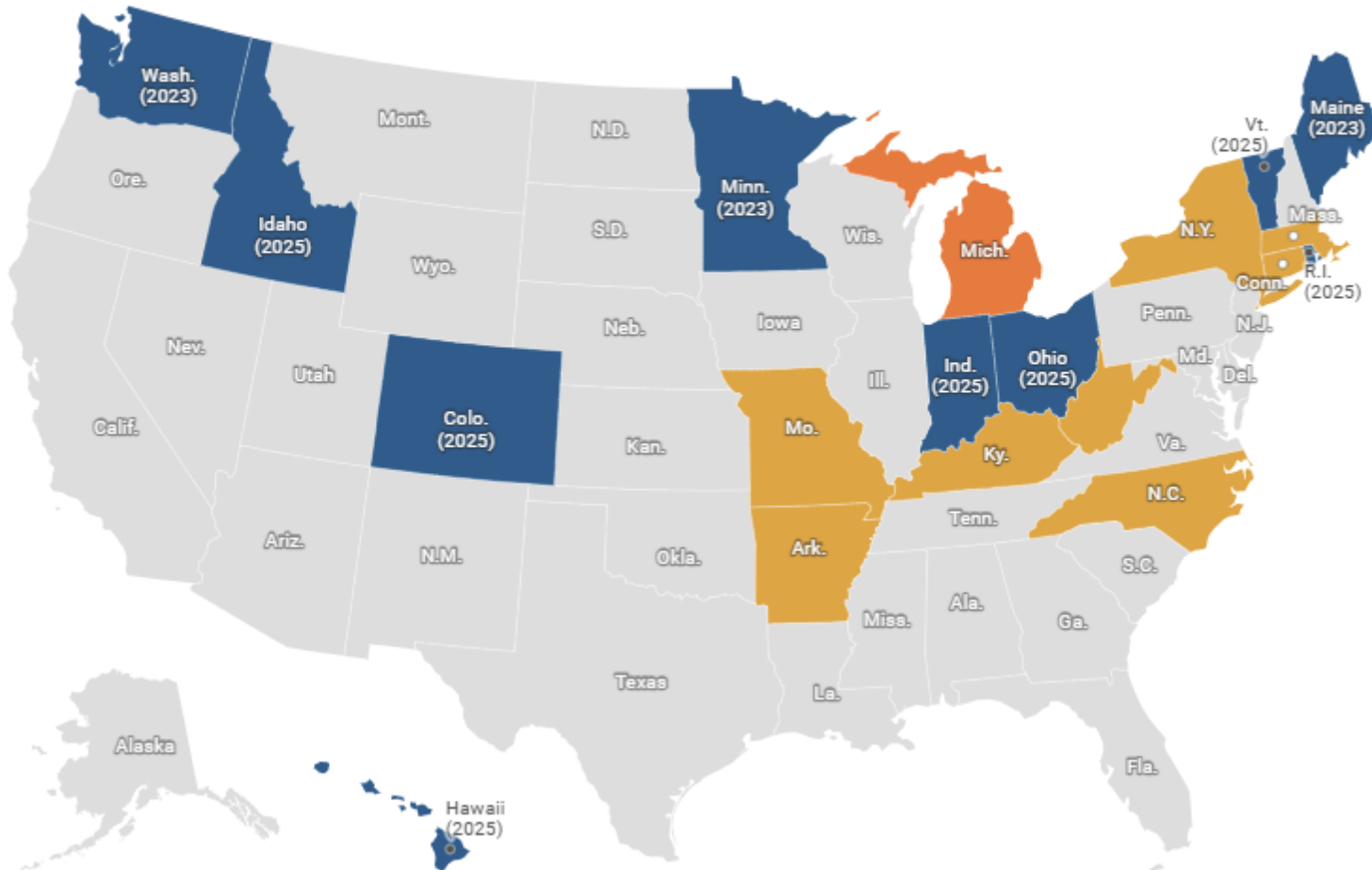
***Tennessee's bill only applies to drugmaker 340B restrictions placed after July 1, 2025.



Provider Reporting Laws Addressing Manufacturer Restrictions

340B REPORT 2025 State Legislation Tracker: 340B Provider Reporting Bills and Laws

■ Provider reporting law passed ■ Bill introduced ■ Bill cleared first legislative chamber ■ Bill with state governor



Source: 340B Report

Contract Pharmacy Addressing Manufacturer Policies



ESP



**Direct
Replenishment**



**Entity-Owned
Pharmacy**

Options available to covered entities to minimize
impact of contract pharmacy restrictions



Contract Pharmacies

Maximizing Your Network



Strategically set designations in ESP & submit data according to manufacturer policy

Partner with prescribers to educate on the benefit of utilizing a contracted pharmacy



Review contract terms including administrative and dispensing fees to ensure alignment with objectives

Monitor store performance to identify unfavorable relationships early on





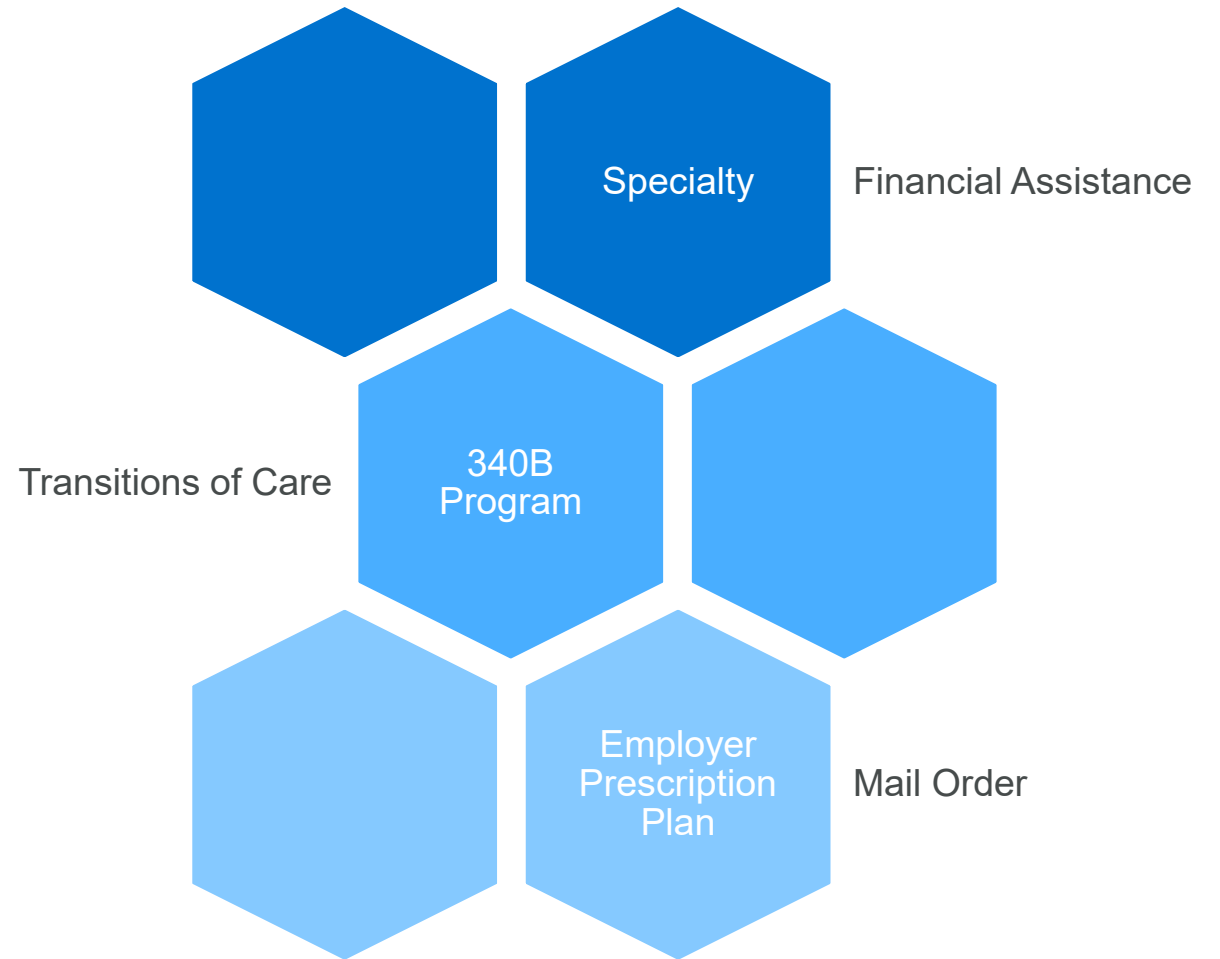
Community Pharmacy

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 & 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 & procedures
- Differences in billing practices by payor
- Communication gaps between providers, patients, & pharmacists



Enhanced Community Care Models

Integration of Pharmacy Services

Pharmacist Led Services

- Medication Therapy Management (MTM)
- Preventative Services
 - Immunizations
 - Point-of-Care Testing (POCT)
 - Routine Health Screenings
- Medication Synchronization
- Medication Adherence Counseling
 - Delivery
 - Compliance Packaging
- Collaborative Disease Therapy Management (CDTM)
- Telepharmacy





Entity-Owned Pharmacy

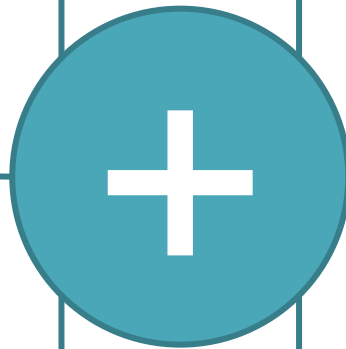
The Benefit of Internalizing Your Prescriptions

The Patient Care Benefit

Continuity & total ownership of care

Patient convenience

Integration of pharmacy with the care team

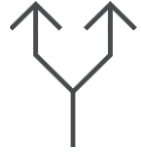


Financial Upsides

Avoid manufacturer restrictions on contract pharmacy arrangements

Additional revenue-generating service line

Potential for additional reimbursable services



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



Group Discussion



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