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340B: The Recent Past, The Stormy Present, the Uncertain Future

Ohio Hospital Association Annual Meeting

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Agenda



1. 340B Brief Overview
2. Covered Entity Compliance and Selected Issues
3. Current Developments and Litigation Topics
4. Future of 340B

340B Brief Overview

340B Overview

Basics



- Created by Section 340B of the Public Health Service Act (42 USC § 256b) (1992)
- Administered by the Office of Pharmacy Affairs (OPA) of the Health Resources and Services Administration (HRSA) in the Department of Health & Human Services (HHS)
- The 340B Program limits the price a manufacturer may charge to “Covered Entities” for “covered outpatient drugs”

340B Overview

Basics

Three key concepts are:

- **Entity Eligibility:**
The definition of “Covered Entities” encompasses entities considered “safety-net providers.” There are 6 categories of hospitals and 10 categories of non-hospital entities (generally PHS grantees).
- **Drug Eligibility:**
340B drugs are “covered outpatient drugs” as defined under the Medicaid Drug Rebate Program (MDRP).
- **Patient Eligibility:**
An individual receiving 340B drugs must be a patient of the covered entity as defined by HRSA.

340B Overview

Basics

■ Locations Eligible for 340B Prescriptions

- Main Hospital (within the 4 walls of the hospital)
- HRSA-registered Child Sites of the Covered Entity
- Contract Pharmacies
 - Pharmacies under compliant contractual relationship with Covered Entity and registered with HRSA as a contract pharmacy



340B Overview

Basics



- **Restrictions on 340B**
- No diversion
 - May not sell or transfer 340B drugs to other entities
 - May not dispense 340B drugs to persons that are not eligible patients
- No “duplicate discount”
 - Drugs purchased through 340B may not generate manufacturer rebates under MDRP
 - Other requirements depending on type of Covered Entity (Medicaid Exclusion File)

340B Overview

Basics

- **Restrictions on 340B (cont.)**
- **GPO Prohibition**
 - Applies to DSH, children's, and free-standing cancer hospitals
 - May not “obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.”
 - Applies to clinics within the four walls of the hospital and registered child sites

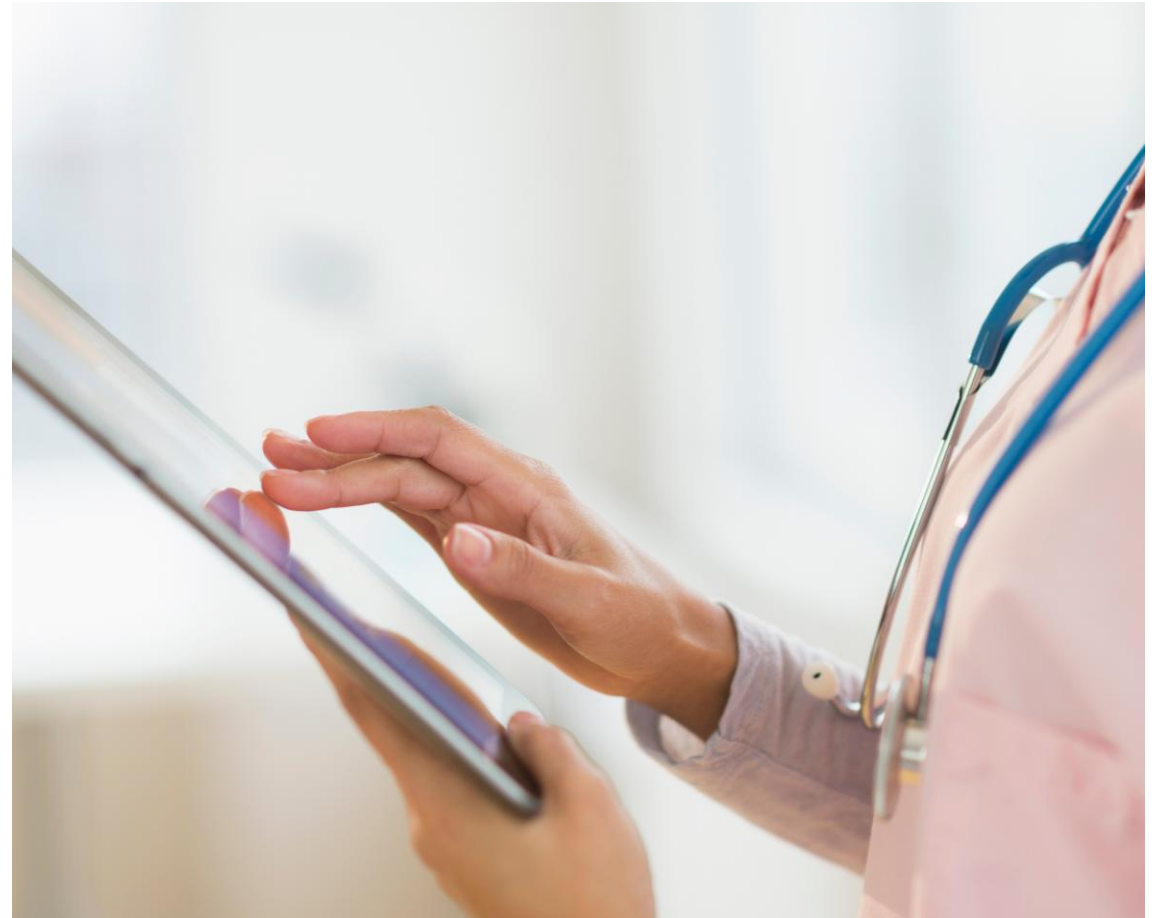


Covered Entity Compliance and Selected Issues

Provider-Based Locations and CoP Compliance

Gateway to Child Site Enrollment

- To enroll as a child site, a location must be enrolled as a hospital outpatient location
- Each location must comply with provider-based rules at 42 CFR 413.65
- Each location subject to hospital conditions of participation at 42 CFR Part 428
- Rapid location conversions can create significant challenges



State Hospital Licenses

A New Element of 340B Compliance

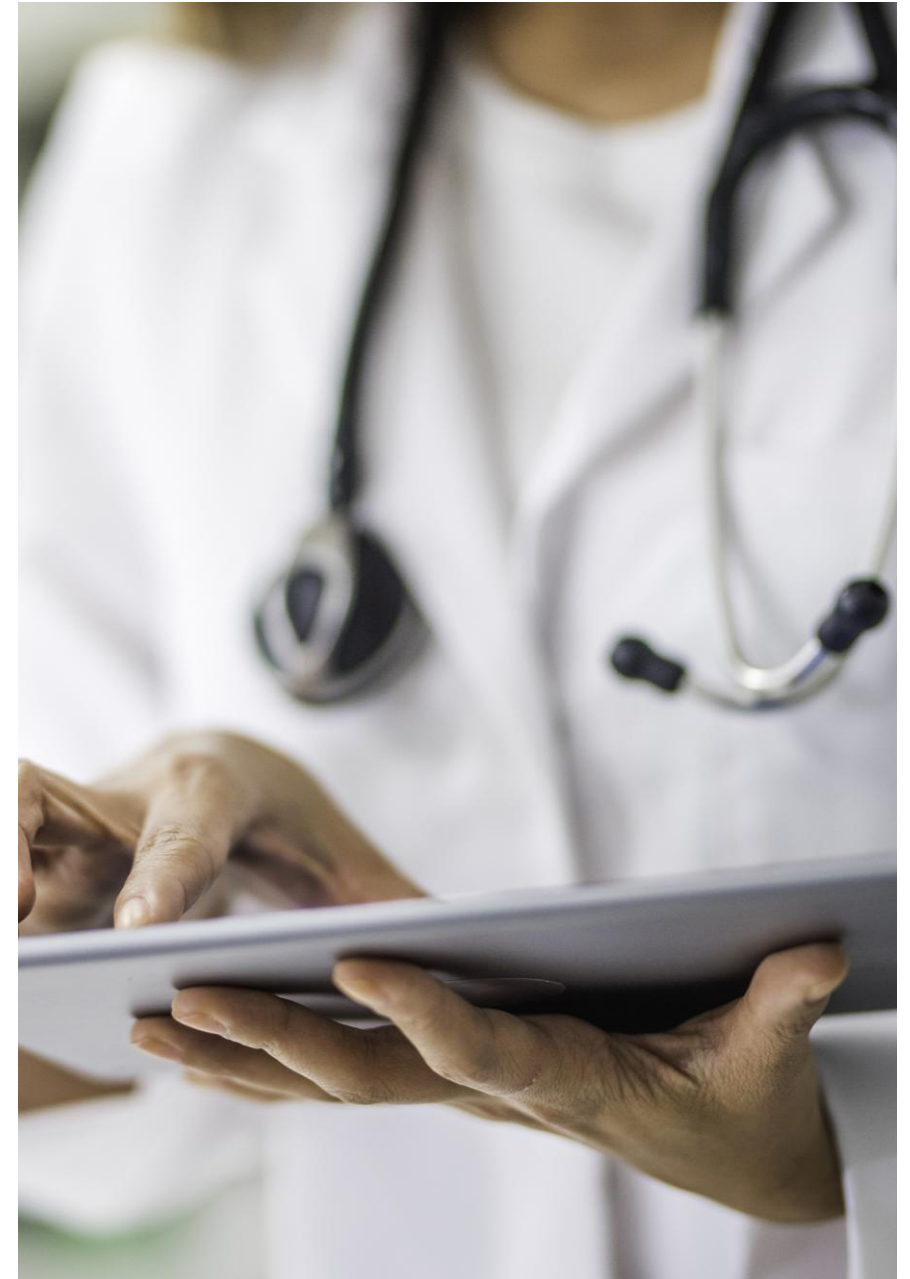


- Element of provider-based requirements – all hospital locations must be licensed as part of the hospital
- Beginning last fall, Ohio licenses hospitals, including all provider-based locations
- “Covered Entity” definition is cross-referenced to Medicare provider enrollment
- Covered Entity service requires patient eligibility, which requires compliance with state hospital licensure laws (e.g., telehealth, home care, etc.)

Medicare Cost Report Issues

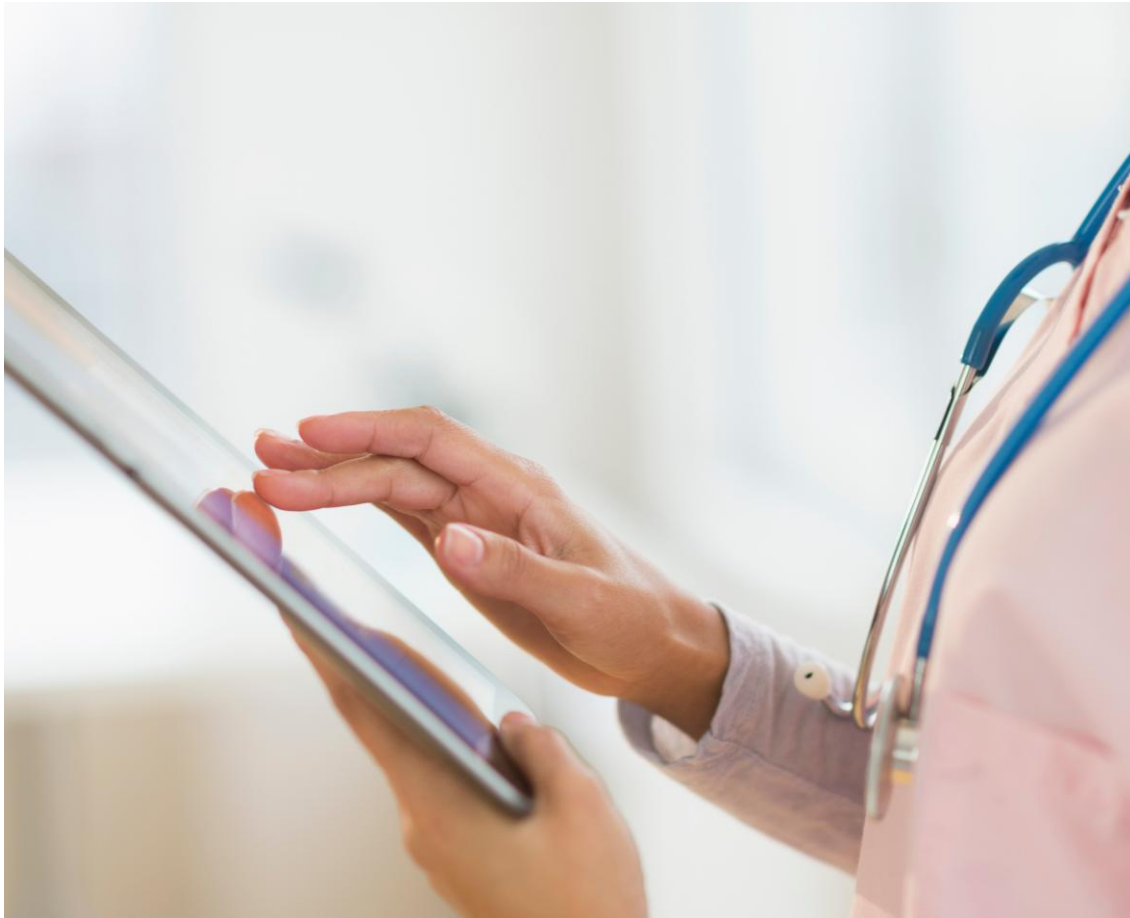
Establishing Covered Entity Eligibility

- Need to demonstrate status as a safety-net provider for low-income patient populations
- DSH patient percentage threshold – 11.75% for disproportionate share hospitals; 8% for sole community hospitals
 - Critical Access Hospitals automatically qualify.
- Must demonstrate percentage on most-recently filed cost report
- Child site costs and charges appearing on a filed cost report



State Pharmacy Licenses

Pre-requisite for hospital drug operations



- All hospital locations stocking and dispensing drugs must comply with applicable state pharmacy licensure rules
- Transfer of drugs within hospital system may give rise to wholesale licensure considerations or distributor licensure (DEA controlled substances)

Current Developments and Litigation Topics

Controversy of 340B

Key Issues

- 340B Statute:
 - The statute does not provide clear definition and parameters for fundamental components of the program including patient eligibility, contract pharmacy, eligible locations, and enforcement
 - HRSA is a relatively small agency, has very limited rulemaking authority
- 340B Program Growth:
 - Over the past decade, the 340B program has grown significantly
 - See [HRSA update on 340B Covered Entity purchases](#)

Controversy of 340B

Key Issues (cont.)

- What is the purpose of the 340B program?
 - Covered Entity Perspective:
 - The 340B program is meant to help Covered Entities offset the cost of caring for the indigent
 - 340B Covered Entities use their savings to improve health care services and lower costs of medicines to vulnerable patient populations
 - Manufacturers Perspective:
 - The purpose of the 340B is to provide is to directly provide vulnerable and uninsured patients access to more affordable medicines
 - 340B growth is due to Covered Entity abuses and results in inflated drug costs and negatively impacts innovation. Discounts are not reaching low-income patients.

Patient Definition

Statute and Genesis Decision

- 340B Statute prohibits “Diversions”:
 - A covered entity may not resell or transfer a 340B drug to a person who is not a “patient” of the entity
 - 1996 Patient Definition Guidelines set forth a multi-pronged definition
 - HRSA’s Unpublished “Prescription Origination” Interpretation
- November 3rd, 2023, South Carolina District Court ruled that HRSA could not enforce its interpretation of the term “patient” as reflected in an audit enforcement letter to Genesis Healthcare, Inc.
 - The letter reflected HRSA’s historic position that the 340B patient’s prescription must originate from a Covered Entity health care service

Contract Pharmacy Developments

Manufacturer Restrictions – Contract Pharmacy Background

- Covered Entities contract with pharmacies to deliver 340B-priced drugs to the Covered Entities' patients
- In 1996, HRSA issued guidance permitting Covered Entities to use one single contract pharmacy
- In 2010, HRSA issued guidance permitting Covered Entities to use multiple contract pharmacies

Contract Pharmacy Restrictions

Manufacturer Restrictions – Litigation

- Citing concerns relating to expansive growth, compliance, and transparency, in 2020, a few large manufacturers began placing limitations on Covered Entities' arrangements with contract pharmacies
 - Limiting shipment of 340B-priced drugs to an in-house pharmacy or a single designated contract pharmacy
 - May condition 340B discounts on submission of data
 - Initial restrictions were for hospital only, but increasingly apply to grantees
- HRSA issued enforcement letters to six drug manufacturers in October 2021; all recipients filed suit

Contract Pharmacy Restrictions

Manufacturer Restrictions – Litigation

- Two Federal Circuit Courts have ruled in favor of manufacturers, finding that the manufacturers had no obligation to provide 340B drug pricing to an unlimited number of contract pharmacies
 - Third Circuit ruled on January 30, 2023
 - D.C. Circuit ruled on May 21, 2024
 - 7th Circuit Court of Appeals decision is still pending
- Today, over 35 manufacturers have imposed contract pharmacy restrictions

Contract Pharmacy Restrictions

Manufacturer Restrictions – Litigation (cont.)

Since the Third Circuit ruled in favor of manufacturers, more manufacturers are imposing restrictions on utilization of contract pharmacies, including restricting Covered Entities to using only one contract pharmacy for certain products



- Establish/grow Covered Entity-owned pharmacy in order to be less dependent on multiple contract pharmacy arrangements; MSA relationships are becoming more common



- Alternative distribution model arrangements
- Establish White Label PBM



- Re-evaluating policies/parameters for identifying eligible patients
 - Expanding use of telemedicine
 - Expanded role of pharmacists (MTM programs)

Contract Pharmacy Restrictions

State Access Bills/Anti-340B Discrimination – Status/Statistics for Other States

- Arkansas 1103:
 - Prohibits drug manufacturers from denying 340B access at Arkansas-based contract pharmacy arrangements
 - On March 12, 2024, the 8th Circuit ruled in favor of the state of Arkansas finding that Arkansas Act 1103 is not preempted by the 340B statute
- Many other states have passed similar laws that are being challenged by drug manufacturers
 - Federal district courts in LA, MD, MS have ruled against manufacturers in lawsuits related to state laws preserving access to multiple contract pharmacies
 - However, a WV district court granted manufacturers a preliminary injunction

New Areas of Litigation

Rebate Model – Background

August 23, 2024, J&J Notice to Disproportionate Share Hospitals

- Commencing October 15, 2024, 340B discounts on Stelara and Xarelto will only be available under a 340B rebate model
- Rebate Model:
 - DSH Covered Entities must purchase products at non-340B price (WAC)
 - After dispensing to 340B eligible patients, may submit rebate claim data (including medical claims data elements) to J&J's vendor's 340B eligibility validation process

September 2024 HRSA Cease and Desist Letters and J&J Response

- HRSA states the rebate model violates the 340B statute unless “approved” by HRSA
- Warns of termination of Pharmaceutical Pricing Agreement and the imposition of civil monetary penalties
- In response to HRSA's communications J&J ceased implementation of the rebate model

New Areas of Litigation

Rebate Model – Current Litigation

Manufacturer Lawsuits

- 4 manufacturers that have filed lawsuits against HRSA to impose a rebate model (Sanofi, Johnson & Johnson, Eli Lilly, and Bristo-Myers Squibb)
- Concern to Covered Entities is that 340B eligibility determination shifts to the manufacturer

Rebate Model and IRA

- IRA requires access to the lower of Maximum Fair Price or 340B price
- Manufacturers have raised duplication concerns if 340B drugs are not identified
- Since manufacturers will provide the MFP through rebates, they are arguing that 340B pricing should also be given via rebates to avoid duplication concerns

Some Republicans in Congress have expressed interest in making the rebate model part of 340B reform

Third Party Payors/PBMs

Medicare Advantage Litigation

- SCOTUS Ruling (2022):
 - CMS's 340B drug reimbursement cuts were unlawful
- CMS Response (2023):
 - Issued retroactive payments to 340B hospitals (2018–2022); MAOs excluded
- Current Dispute
 - Hospitals seek MAO reimbursement; MAOs argue contracts don't require it
- Key Legal Issues:
 - Contractual references to Medicare rates and CMS policy
 - MAOs claim retroactive payments are not required absent express terms
 - Hospitals cite parity requirements and unjust enrichment

Third Party Payors/PBMs

PBM Requirements and Reimbursement

- PBMs may require that pharmacies:
 - Provide information on 340B utilization during the credentialing process
 - Participate in special pharmacy networks if they primarily dispense 340B prescriptions
 - “Flag” 340B dispensing by using identifiers
 - Accept lower reimbursement when dispensing 340B
- Over 30 states have passed laws to prohibit discriminatory reimbursement of 340B drugs
 - Ohio Rev. Code § 3902.71.
 - ERISA and Part D Preemption Arguments

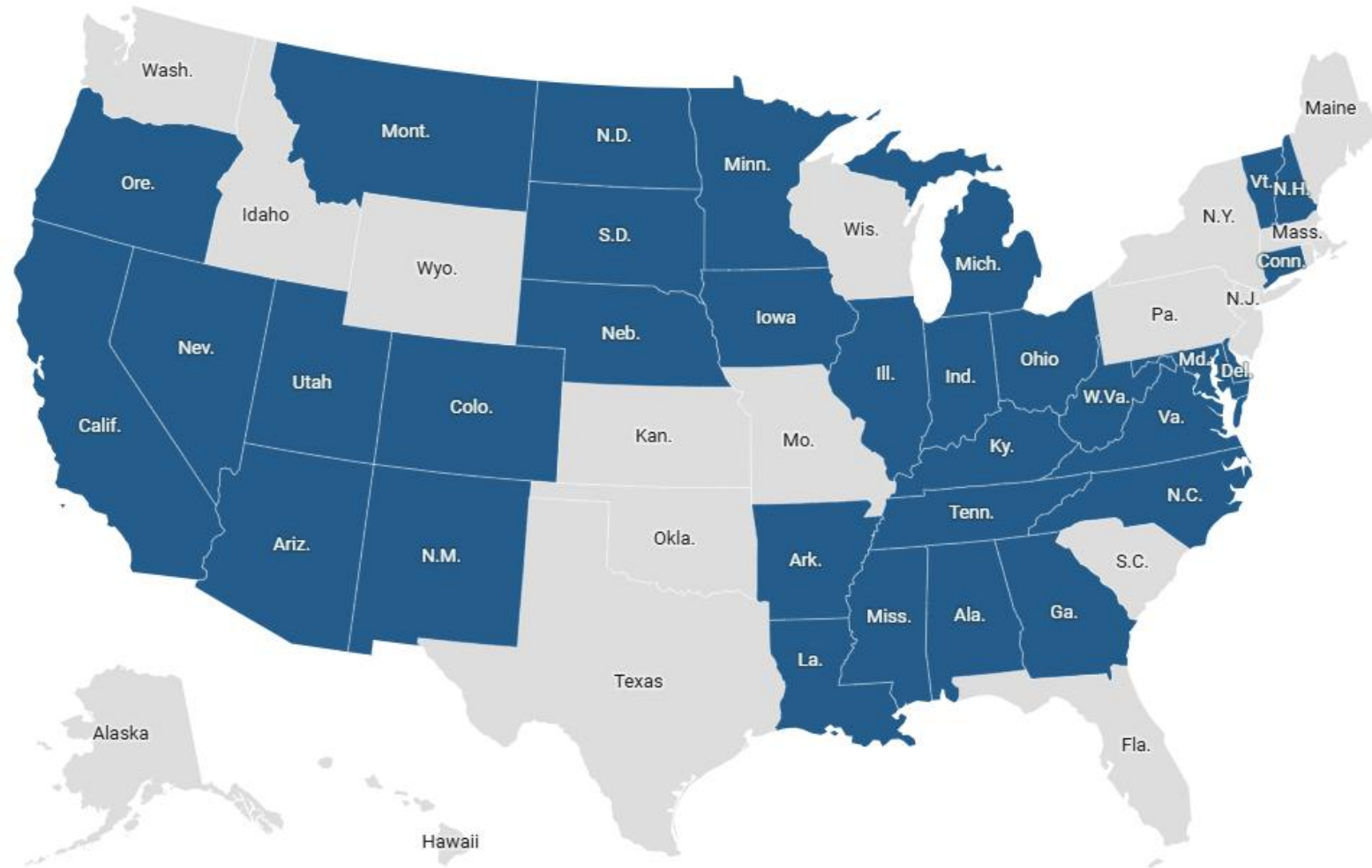
Third Party Payors/PBMs

340B Stakeholder Perspective

- Comments submitted to FTC
 - Target PBM-affiliated contract pharmacies and PBM reimbursement practices as exploiting the 340B program to earn outsized profits meant for safety-net providers
- Covered entity concerns:
 - PBMs/Plans are not intended beneficiaries of the 340B discount
 - Distrust (and in some cases a misunderstanding) regarding the purpose of identifiers
 - PBM-affiliated specialty pharmacies using leverage to force covered entities to accept high dispensing fees

340B Report: 2025 State Legislation Tracker

Laws Enacted that Bar PBMs from Differentially Reimbursing 340B Providers



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Map: updated as of March 20, 2025 • Created with [Datawrapper](#)

Future of 340B

340B Outlook

Regulatory and Legislative Activity

White House

Try again to reduce hospital Part B reimbursement for 340B drugs?

Move the 340B Program from HRSA to CMS?

Approve the rebate model (or a more limited version)?

Congress

4.24.25 Cassidy Report

SUSTAIN ACT (Bipartisan Senate 340B Working Group)

PROTECT 340B Act (H.R. 2534)

340B ACCESS Act (H.R. 8574)

States

Anti-Payer/PBM Discrimination of 340B Laws

340B Contract Pharmacy Access Laws

340B Provider Reporting Laws

Questions?



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Thank you!