

# 340B IN MAINE

PDAB Briefing  
March 24, 2025



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# What is the 340B Drug Pricing Program?

The federal 340B Program allows qualifying providers to purchase outpatient drugs at a discount.

The savings from those discounts are used to help these providers serve their communities, **at no cost to taxpayers or the government.**

The program enables covered entities to stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services.

## Program Background

In 1992 Congress enacted the Public Health Service Act, which created the 340B Program; this required drug manufacturers to participate as a condition of having their outpatient drugs covered under Medicaid and Medicare Part B. Section 340B of the Public Health Service Act requires manufacturers to offer health care organizations that care for many uninsured and low-income patients covered outpatient drugs for purchase at discounted prices.

## Who is eligible for 340B discounts?

Eligible health care organizations (also known as “covered entities”) are defined in statute and include Federally Qualified Health Centers (FQHCs), Critical Access Hospitals, Disproportionate Share Hospitals, children’s hospitals, Sole Community Hospitals, Ryan White clinics and State AIDS Drug Assistance programs, and other safety net providers.

## Who oversees 340B?

The 340B program is heavily regulated with both state and federal oversight. It includes compliance mechanisms, penalties for noncompliance or abuse and a dispute resolution process. To participate in the 340B Program, “covered entities” must register and be enrolled with the Health Resources and Services Administration within the U.S. Department of Health and Human Services and comply with all 340B Program requirements (annual recertification, annual Medicare cost reports, IRS filings, provider audits and more). Through this thorough process, “covered entities” demonstrate that they use their savings to benefit patients and communities.

# What is the 340B Drug Pricing Program?

## 340B Ensures Access to Essential Health Care for Rural and Underserved Mainers

340B savings enable safety-net providers to offer health care services and support to patients in need that they otherwise could not provide. Safety-net providers work hard to tailor services to the specific needs of the patients and communities they serve.

- **Comprehensive diabetes programs and insulin availability**
- **Cancer treatment programs and prevention**
- **Behavioral and mental health care**
- **Workforce (community health workforce, support staff, outreach & enrollment, etc.)**
- **Access to free and discounted drugs**
- **HIV/AIDS care**
- **Substance use disorder treatment**
- **Wrap around services including transportation, heating assistance, and food pantries**
- **And so much more...**






# What is the 340B Drug Pricing Program?

Maine's FQHCs and Hospitals are eligible to participate in 340B.

The savings are being used by Maine providers as Congress intended.

Both State and Federal Law require transparency. Maine has been a leader on this.



Coalition to Protect Health Care for Rural and Underserved Communities

## 340B Program Integrity

The 340B program is heavily regulated with both state and federal oversight. It includes compliance mechanisms, penalties for noncompliance or abuse and a dispute resolution process. Covered entities that participate in the program may only purchase 340B discounted drugs for patients who qualify and may not receive duplicative 340B discounts and Medicaid rebates for the same drug. Additionally, covered entities may not engage in diversion of covered outpatient drugs defined by Health Resources and Services Administration (HRSA) as the resale or other transfer of a 340B drug to ineligible patients.

➔ **Compliance & Audits**

- Both the Secretary of U.S. Department of Health and Human Services (DHHS) and drug manufacturers are authorized to audit covered entities to ensure compliance with the diversion and duplicate discount provisions.
- Covered entities that fail to comply may be fined and/or removed from the program.

➔ **Federal Preemption & Oversight**

- No state has adopted redundant program integrity provisions and any attempt to enforce the provisions in the 340B program raise federal preemption concerns.
- In the words of a federal district court in Mississippi, the 340B Program has "comprehensive enforcement mechanisms."
- When it was alleged that federal oversight of the 340B program needed enhancement, even the Supreme Court agreed that enforcement of the 340B program is robust.

### Key Components of 340B Program Integrity in Maine

*Details on reverse*

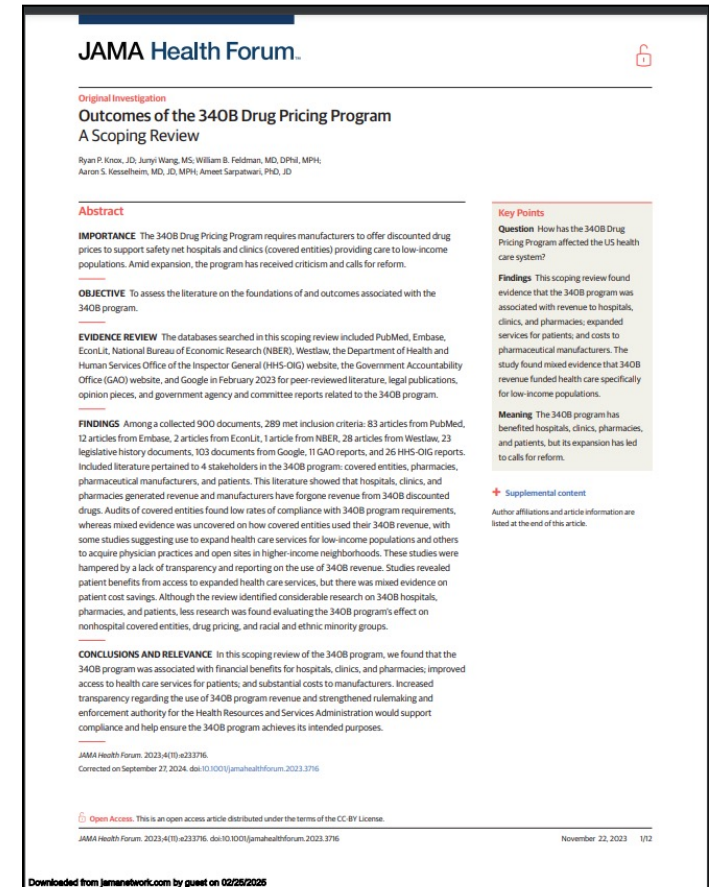
Federal Oversight	State Oversight
<b>1</b> HRSA is the lead federal agency providing the bulk of oversight of this program.	<b>3</b> MaineCare provides some regulatory oversight to the extent that it overlaps with MaineCare drug discount programs.
<b>2</b> HRSA has specific provisions for FQHC providers.	<b>4</b> MHDO has specific transparency regulations for hospital providers.

For over 30 years, the 340B Program has increased access to care for rural and underserved communities. Efforts to restrict this program only serve to increase profits for pharmaceutical companies at the expense of patient care across Maine.

# What is the 340B Drug Pricing Program?

A “meta” study that was published on the National Institute of Health website is the best resource on this issue. A meta study summarizes the findings of multiple studies of a topic. The 340B meta study appeared in the JAMA Health Policy Forum. It reviewed 900 documents and ultimately included a review of 283 different studies.

***“The findings of this study demonstrate that the 340B program offers value to many stakeholders in the US health care system. Studies have shown that many covered entities used 340B revenue to provide additional health services to patients, subsidize uncompensated and charity care, and provide free or low-cost medications to patients. These findings should be considered against the increasing criticism of the 340B program. ... our findings show that the 340B program has been successful in aiding safety net hospitals and clinics serving low-income and underserved populations and that the consequences of eliminating or substantially restricting the program would be great.”***



# 340B at Risk

Starting in 2020, PhRMA members have placed several restrictive and discriminatory requirements on 340B entities, resulting in **tens of millions in lost savings for Maine's safety-net providers.**

One tactic has been discriminating against pharmacies ("contract pharmacies") who chose to partner with hospitals and FQHCs that participate in the 340B program.

FIRST OPINION

## Pursuit of profits is driving drug companies to break the 340B law

By Maureen Testoni June 10, 2022

[Reprints](#)



ADOBE

**S**eventeen drug companies, including some of the world's largest, are flouting a 30-year-old federal program that supports hospitals serving patients with low incomes and those who live in rural communities. Both the [Trump](#) and [Biden](#) administrations have deemed these actions unlawful. But these drugmakers continue to ignore the law, sapping resources from the nation's health care safety net and threatening the health of the patients who rely on it

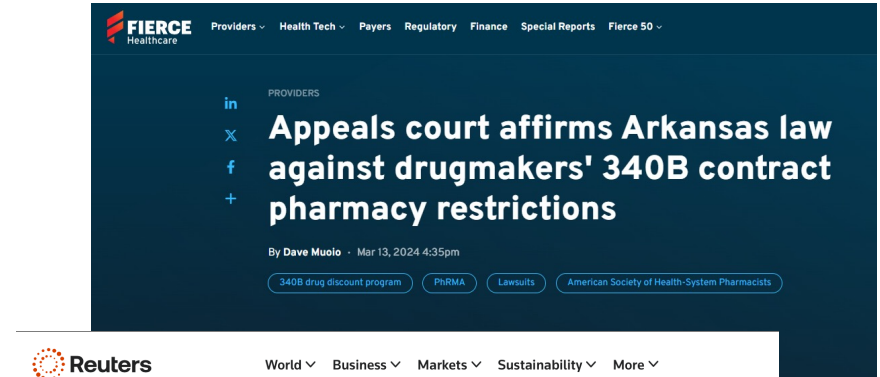
# 340B at Risk

The federal oversight entity, the Health Resources and Services Administration (HRSA), attempted to protect provider – pharmacy partnerships. HRSA lost in 2022.

That’s when states decided to act to protect in-state providers against discrimination.

Arkansas led the way. In 2023, following the passage of their legislation several contract pharmacy restrictions were rescinded. Arkansas law has been upheld, all the way to Supreme Court.

Many other states - both “red” & “blue”- have followed.



World Business Markets Sustainability More

## US Supreme Court will not hear drug industry challenge to Arkansas contract pharmacy law

By Brendan Pierson

December 9, 2024 4:08 PM EST · Upd

Modern  
Healthcare

NEWS BLOGS OPINION EVENTS & AWARDS MULTIMEDIA DATA & INSIGHTS

December 13, 2024 05:00 AM

## Supreme Court's silence fortifies 340B contract pharmacy laws

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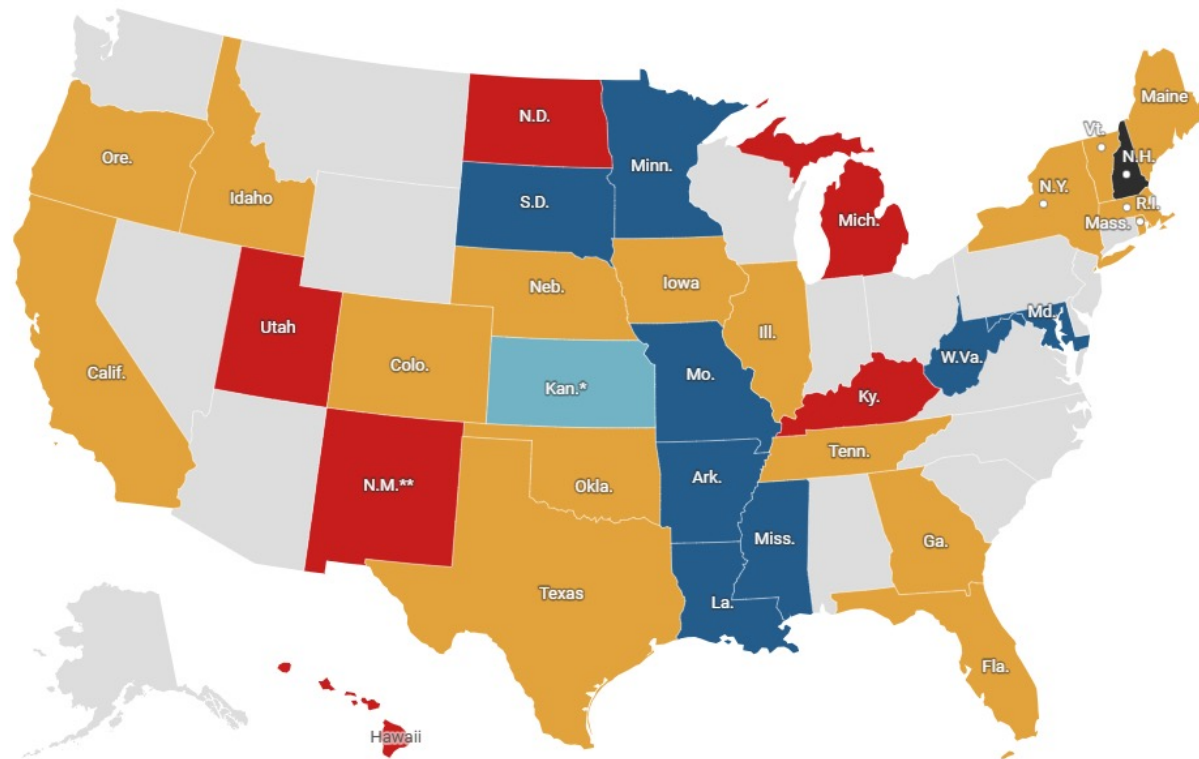


# 340B at Risk



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

■ Law passed ■ Bill introduced in 2025 ■ Bill cleared legislative chamber ■ Bill died in 2025



\* Kansas enacted 340B contract pharmacy access provisions in 2024, but the state attorney general argued in federal court that the law is unenforceable and does not "prohibit or forbid anything."

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

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Map: updated as of March 17, 2025 • Created with [Datawrapper](#)



## An Act to Protect Health Care for Rural and Underserved Areas by Prohibiting Discrimination by Participants in a Federal Drug Discount Program

- The legislation requires PhRMA (and PBMs) to honor the 340B price at partner pharmacies.
- It gives enforcement to the Attorney General.
- It preserves savings for the Medicaid program.

### Sponsors

Senator Donna Bailey (D-York)  
Representative Joshua Morris (R-Turner)  
Representative Robert W. Nutting (R-Oakland)  
President Matthea Daughtry (D-Cumberland)  
Representative Anne-Marie Mastraccio (D-Sanford)  
Senator Marianne Moore (R-Washington)  
Senator Joseph Baldacci (D-Penobscot)  
Representative John E. Ducharme III (R-Madison)  
Representative Ann Fredericks (R-Sanford)

# LD 1018

## The Coalition to Protect Health Care for Rural and Underserved Communities

The Coalition is comprised of:

1. Maine's Federally Qualified Health Centers (FQHCs)
2. Maine Hospitals
3. Maine's Pharmacies and Health System Pharmacists



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**Contact:** Amy Downing, [amy@mainepharmacy.org](mailto:amy@mainepharmacy.org)  
Organization representing individual pharmacists in the state.