PROTECT 340B

Legislative Briefing
March 4, 2025

The Coalition to Protect Health Care
for Rural and Underserved Communities

Maine Primary Care Association

MHA Maine Hospital Association

mshp Maine Society of Health System Pharmacists

Rx Maine Pharmacy Association

Outline

1. Who We Are
2. What is the 340B Drug Pricing Program?
3. What Does it Mean for Maine?
4. Why is 340B at Risk?
5. What the Legislation Does
6. What the Other Side is Saying
7. Questions & Contacts

Who We Are

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

Maine's FQHCs and Hospitals are eligible to participate in a federal wholesale drug discount program known as 340B.

Maine Primary Care Association

Contact: Hannah Hudson, hhudson@mepca.org
Organization representing Maine's FQHCs (Community Health Centers).

MHA Maine Hospital Association

Contact: Jeff Austin, jaustin@themha.org
Organization representing community-governed hospitals in Maine

mshp MAINE SOCIETY OF HEALTH SYSTEM PHARMACISTS

Contact: Amy Downing, amy@maineshp.org
Organization supporting pharmacists in organized health care settings.

MAINE PHARMACY ASSOCIATION

Contact: Amy Downing, amy@mainepharmacy.org
Organization representing individual pharmacists in the state.

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?

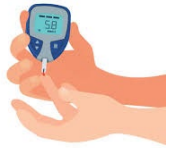
340B Ensures Access to Essential Health Care for Rural and Underserved Mainers

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?

Important Point #1

This program does **NOT** change the retail price of the drugs at partner pharmacies.

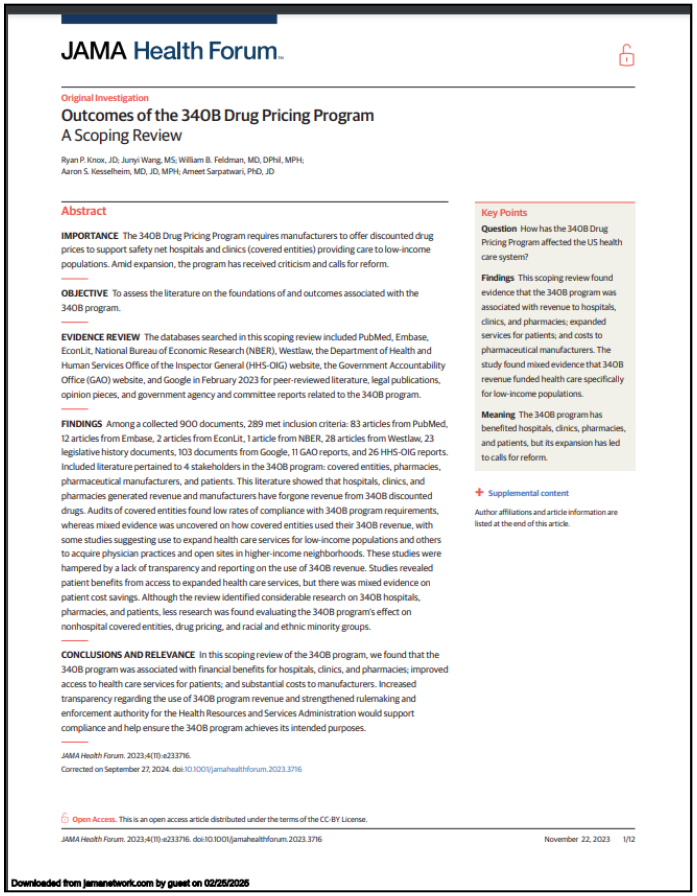
Important Point #2

PhRMA provides the subsidy to FQHCs and Hospitals.
PhRMA wins if the bill dies.

What Does it Mean for Maine?

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.***”



JAMA Health Forum

Original Investigation

Outcomes of the 340B Drug Pricing Program
A Scoping Review

Ryan P. Knox, JD; Junyi Wang, MS; William B. Feldman, MD, DPhil, MPH; Aaron S. Kesselheim, MD, JD, MPH; Ameet Sarpatwari, PhD, JD

Abstract

IMPORTANCE The 340B Drug Pricing Program requires manufacturers to offer discounted drug prices to support safety net hospitals and clinics (covered entities) providing care to low-income populations. Amid expansion, the program has received criticism and calls for reform.

OBJECTIVE To assess the literature on the foundations of and outcomes associated with the 340B program.

EVIDENCE REVIEW The databases searched in this scoping review included PubMed, Embase, EconLit, National Bureau of Economic Research (NBER), Westlaw, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) website, the Government Accountability Office (GAO) website, and Google in February 2023 for peer-reviewed literature, legal publications, opinion pieces, and government agency and committee reports related to the 340B program.

FINDINGS Among a collected 900 documents, 289 met inclusion criteria: 83 articles from PubMed, 12 articles from Embase, 2 articles from EconLit, 1 article from NBER, 28 articles from Westlaw, 23 legislative history documents, 103 documents from Google, 11 GAO reports, and 26 HHS-OIG reports. Included literature pertained to 4 stakeholders in the 340B program: covered entities, pharmacies, pharmaceutical manufacturers, and patients. This literature showed that hospitals, clinics, and pharmacies generated revenue and manufacturers have forgone revenue from 340B discounted drugs. Audits of covered entities found low rates of compliance with 340B program requirements, whereas mixed evidence was uncovered on how covered entities used their 340B revenue, with some studies suggesting use to expand health care services for low-income populations and others to acquire physician practices and open sites in higher-income neighborhoods. These studies were hampered by a lack of transparency and reporting on the use of 340B revenue. Studies revealed patient benefits from access to expanded health care services, but there was mixed evidence on patient cost savings. Although the review identified considerable research on 340B hospitals, pharmacies, and patients, less research was found evaluating the 340B program's effect on nonhospital covered entities, drug pricing, and racial and ethnic minority groups.

CONCLUSIONS AND RELEVANCE In this scoping review of the 340B program, we found that the 340B program was associated with financial benefits for hospitals, clinics, and pharmacies; improved access to health care services for patients; and substantial costs to manufacturers. Increased transparency regarding the use of 340B program revenue and strengthened rulemaking and enforcement authority for the Health Resources and Services Administration would support compliance and help ensure the 340B program achieves its intended purposes.

Key Points

Question How has the 340B Drug Pricing Program affected the US health care system?

Findings This scoping review found evidence that the 340B program was associated with revenue to hospitals, clinics, and pharmacies; expanded services for patients; and costs to pharmaceutical manufacturers. The study found mixed evidence that 340B revenue funded health care specifically for low-income populations.

Meaning The 340B program has benefited hospitals, clinics, pharmacies, and patients, but its expansion has led to calls for reform.

Supplemental content

Author affiliations and article information are listed at the end of this article.

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Corrected on September 27, 2024. doi:10.1001/jamahealthforum.2023.3716

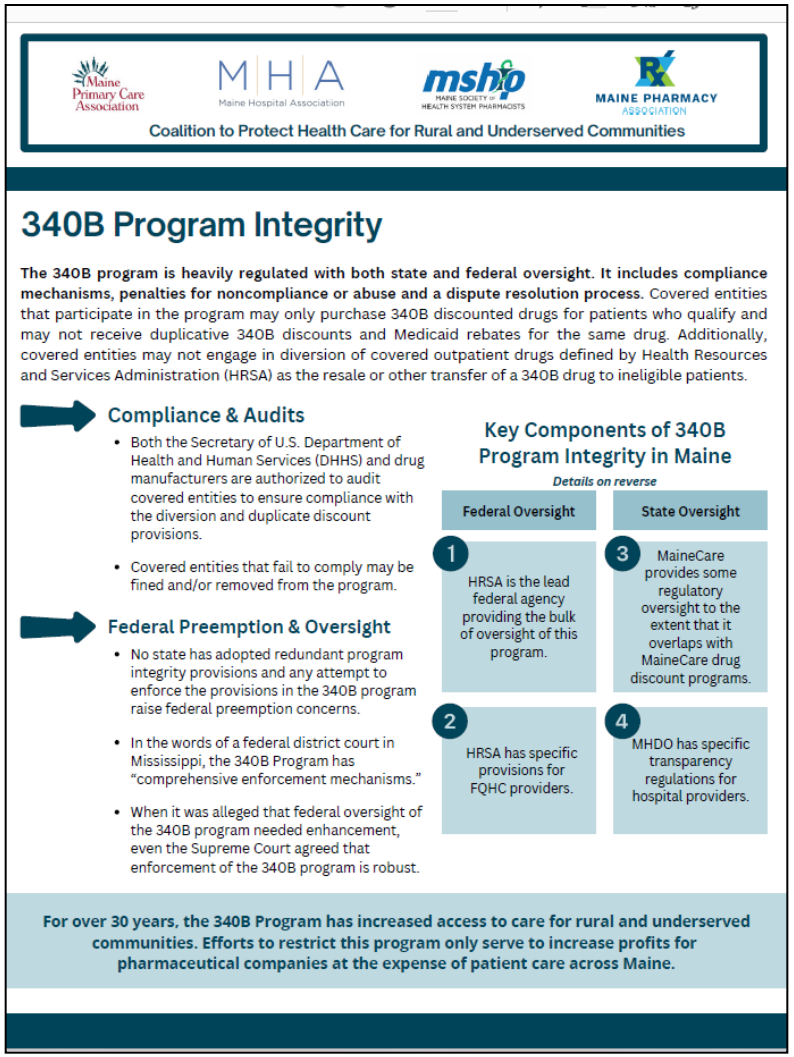
What Does it Mean for Maine?

Important Point #3

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

Important Point #4

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
1 HRSA is the lead federal agency providing the bulk of oversight of this program.	3 MaineCare provides some regulatory oversight to the extent that it overlaps with MaineCare drug discount programs.
2 HRSA has specific provisions for FQHC providers.	4 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.

Why is 340B at Risk?

Starting in 2020, PhRMA members have placed several restrictive and discriminatory requirements on 340B entities, resulting in **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

Seventeen 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

Why is 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 take action.

The 340B 'Saga' Continued: HRSA, States, and Drug Manufacturers Contest 340B Contract Pharmacy Restrictions in Court

by: Douglas A. Grimm, Stephanie Trunk, Gayland O. Hethcoat II of ArentFox Schiff LLP *Health Care Counsel Blog*

Posted On Wednesday, June 26, 2024

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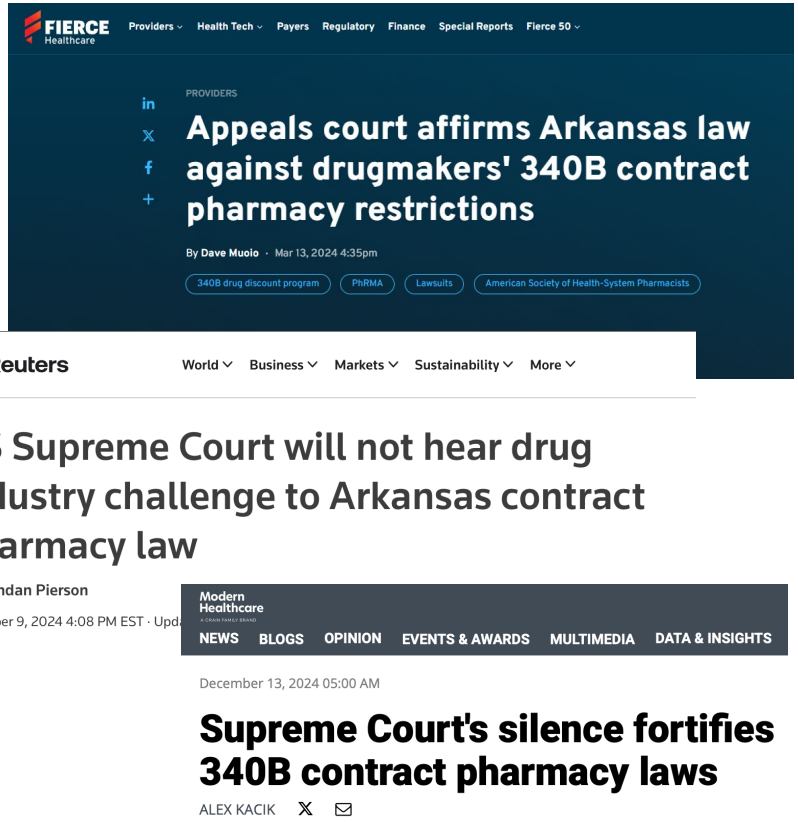
In 2021, we provided an overview of multiple federal lawsuits challenging the US Department of Health and Human Services (HHS) Health Resources and Services Administration's (HRSA) enforcement of the 340B Drug Pricing Program, particularly with respect to contract pharmacies. Three years later, the "340B Saga" continues. Here are some key updates.

Why is 340B at Risk?

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.

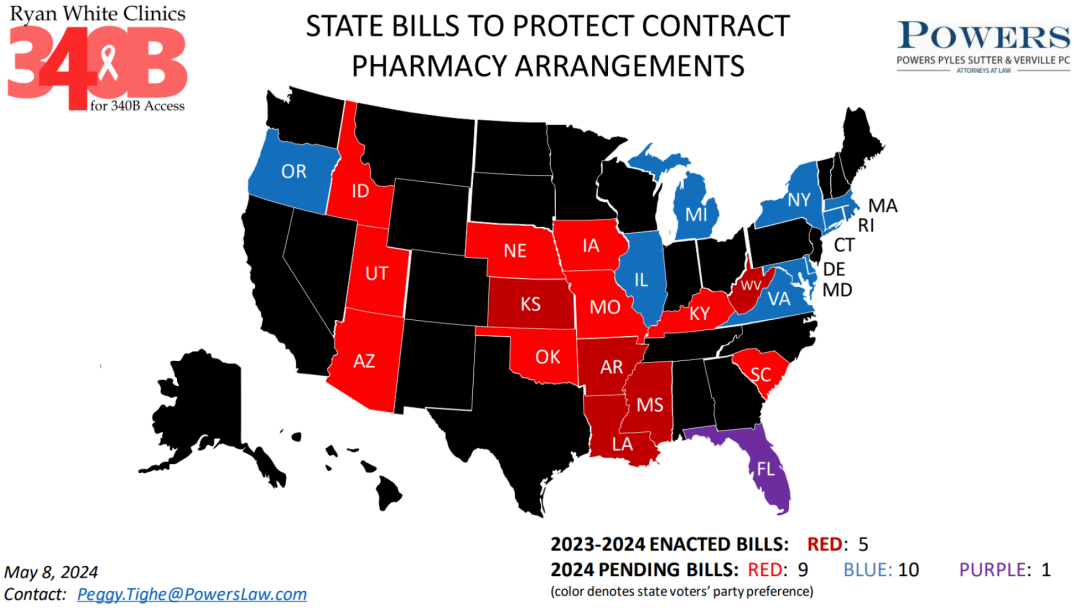


Why is 340B at Risk?

Important Point #5

States may act to protect in-state providers against discrimination.

State Bills to Protect Contract Pharmacy Arrangements

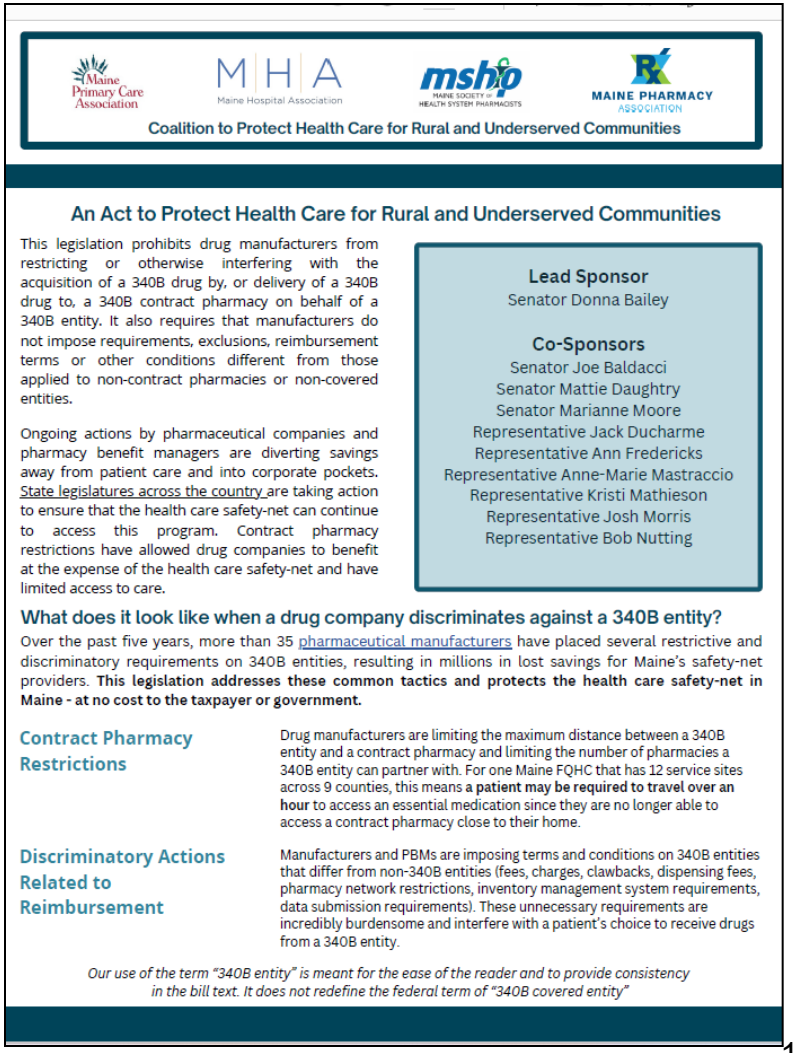


What the Legislation Does

The legislation requires PhRMA (and carriers and PBMs) to honor the 340B price at partner pharmacies.

It gives enforcement to the Attorney General.

It preserves savings for Medicaid program.



Coalition to Protect Health Care for Rural and Underserved Communities

An Act to Protect Health Care for Rural and Underserved Communities

This legislation prohibits drug manufacturers from restricting or otherwise interfering with the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B contract pharmacy on behalf of a 340B entity. It also requires that manufacturers do not impose requirements, exclusions, reimbursement terms or other conditions different from those applied to non-contract pharmacies or non-covered entities.

Ongoing actions by pharmaceutical companies and pharmacy benefit managers are diverting savings away from patient care and into corporate pockets. State legislatures across the country are taking action to ensure that the health care safety-net can continue to access this program. Contract pharmacy restrictions have allowed drug companies to benefit at the expense of the health care safety-net and have limited access to care.

Lead Sponsor
Senator Donna Bailey

Co-Sponsors
Senator Joe Baldacci
Senator Mattie Daughtry
Senator Marianne Moore
Representative Jack Ducharme
Representative Ann Fredericks
Representative Anne-Marie Mastraccio
Representative Kristi Mathieson
Representative Josh Morris
Representative Bob Nutting

What does it look like when a drug company discriminates against a 340B entity?

Over the past five years, more than 35 pharmaceutical manufacturers have placed several restrictive and discriminatory requirements on 340B entities, resulting in millions in lost savings for Maine's safety-net providers. **This legislation addresses these common tactics and protects the health care safety-net in Maine - at no cost to the taxpayer or government.**

Contract Pharmacy Restrictions

Drug manufacturers are limiting the maximum distance between a 340B entity and a contract pharmacy and limiting the number of pharmacies a 340B entity can partner with. For one Maine FQHC that has 12 service sites across 9 counties, this means **a patient may be required to travel over an hour** to access an essential medication since they are no longer able to access a contract pharmacy close to their home.

Discriminatory Actions Related to Reimbursement

Manufacturers and PBMs are imposing terms and conditions on 340B entities that differ from non-340B entities (fees, charges, clawbacks, dispensing fees, pharmacy network restrictions, inventory management system requirements, data submission requirements). These unnecessary requirements are incredibly burdensome and interfere with a patient's choice to receive drugs from a 340B entity.

Our use of the term "340B entity" is meant for the ease of the reader and to provide consistency in the bill text. It does not redefine the federal term of "340B covered entity"

What the Other Side is Saying

PhRMA will throw a lot at this legislation.

If they can kill it, they can continue to reduce the savings they are supposed to give to Maine providers.

Coalition to Protect Health Care for Rural and Underserved Communities

For over 30 years, the 340B Drug Pricing 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.

MYTHS VS FACTS

340B was intended to deliver discounted drugs directly to patients.

340B was created to allow safety-net providers to outpatient medicines for less. They use the savings resources so they can provide a variety of services, better care to patients who can't always pay.

340B uses taxpayer money.

340B is not funded by taxpayers. Instead, drug com drugs to providers at discounted prices, allowing th their existing funding even further. A government a Office of Pharmacy Affairs, receives a small congre appropriation to administer the program.

Contract pharmacy legislation will increase health care costs for employers and state & local government due to lost rebates.

In reality, pharmaceutical companies have entered *voluntary* rebate agreements with Pharmacy Bene (PBMs) for a long time. PBMs can negotiate in cont much, if any, of the rebates received from PhRMA w on to the payer. PhRMA has falsely claimed that Ma are losing millions in foregone rebates due to the 34 (without proving any sources for their data).

Too many providers qualify for 340B.

Congress expanded the roster of eligible entities in the program was not reaching enough providers.

340B covered entities "mark up" the amounts they charge for dispensing 340B drugs, driving up costs.

Payers do not reimburse covered entities any mor drugs than they do for non-340B drugs and contra do not set pricing based on 340B. The differences acquisition costs and reimbursements generate sav safety-net providers when they use eligible drugs f commercially insured patients.

Partnerships with community and specialty contrac generate additional savings. This is precisely how C intended the program to work, creating savings tha reinvested into care for low-income and rural patie

340B also helps restrain drug costs due to penalties drugmakers that repeatedly increase their prescrip prices faster than inflation, resulting in an estimate reduction over 5 years in Medicare Part D spending

Source: 340B Coalition, Maine Hospital Association, M

Coalition to Protect Health Care for Rural and Underserved Communities

MYTHS VS FACTS

Hospitals already have enough money.

For-profit hospitals are ineligible for 340B. Only public and nonprofit hospitals that serve large numbers of Medicaid and low-income Medicare patients or are in rural areas qualify. Many of these providers operate at a loss. In Maine, 28 hospitals qualify for the program and in the most recent year these hospitals:

- Barely broke even in the aggregate; 12 of the 28 lost money
- Provided almost $200 million in uncompensated care (charity care & bad debt)
- Would have lost a combined $220 million without 340B savings
- Have seen their 340B savings reduced by 20% in the past few years

340B hospitals provide less charity care than average.

Compared to non-340B acute care hospitals, 340B DSH hospitals provide more than twice as much care to Medicaid and low-income Medicare patients. In Maine, 340B hospitals continue to provide tens of millions in uncompensated care, despite being in a financially precarious position.

340B covered entities prioritize contract pharmacy agreements in wealthy areas where they can maximize profit out-of-state, rather than underserved areas.

Rural areas across Maine are seeing increased pharmacy deserts and this is not the fault of the covered entity or a side effect of the 340B program. In fact, having access to a 340B contract pharmacy provides a chance for a pharmacy in a rural area to be more viable as that pharmacy receive a small amount more in reimbursement.

PBMs have largely moved to a national consolidated model for specialty and mail order and have limited networks in their insurance plans to drive patients to those locations.

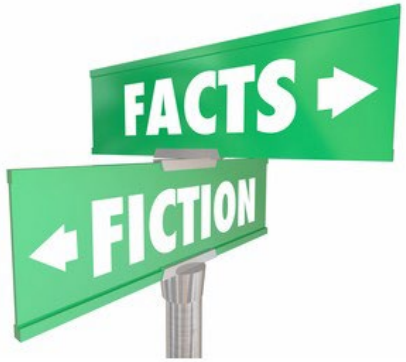
Pharmaceutical manufacturers have limited which pharmacies in the country can buy and dispense their drugs (this is called limited distribution) and *are forcing* some 340B covered entities to enter into out of state contracts to access necessary medications for their patients.

Community Health Centers (FQHCs) don't need 340B because they are federally funded.

In Maine, federal Section 330 funds only account for 5-15% of a CHC's operating budget. The 340B program is critical to ensuring that communities have access to important care and resources. Across Maine, CHCs have lost millions due to the restrictions imposed by pharmaceutical manufacturers on 340B since 2020.

"An Act to Protect Health Care for Rural and Underserved Communities" keeps 340B savings in Maine where they belong, supporting our safety-net healthcare providers, rather than being diverted to the pockets of out of state pharmaceutical manufacturers.

Source: 340B Coalition, Maine Hospital Association, Maine Primary Care Association



For all the mud they throw - just ask:

How does killing this bill help Maine?

What the Other Side is Saying

Let us briefly address a few of the claims all of which are either false, misleading or a distraction:

340B Blocks $50M in Employer Rebates.

- These are not real numbers. PhRMA has no Maine data to substantiate. PhRMA is trying to access this information, including protected health information, to further limit access to 340B savings.
- PhRMA voluntarily provides rebates to PBMs for more favorable terms like getting on a formulary, and PBMs then use the rebates to bargain with payers.
- The largest self-insured plan in the state has not received a reduction in rebates due to 340B. Even if it were true, should Maine trade $300M in 340B provider savings for $50M in potential rebates for employers?

340B Doesn't Benefit Patients Because Hospital Savings aren't Earmarked to X, Y, and Z…

- Congress specifically chose not to micromanage the savings. The intent of the program is to "*stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services*."
- Maine 340B hospitals provide $200M in uncompensated care last year alone, and they disproportionately serve Medicaid and Medicaid patients – often at a loss. The 340B hospitals in Maine barely break even.
- The savings are serving the mission of our non-profit hospitals.
- Maine's transparency law will show you where 340B savings are being invested and our two largest health care systems already have public websites: MaineHealth and Northern Light Health.

340B incentivizes covered entities to mark up of prices.

- Hospitals and FQHCs do not control the prices of retail pharmacy sales, and, for hospitals who have retail pharmacies, the price of a drug is the same for all patients.
- The price paid by the patient is determined by their insurance coverage.
- Payers determine what drugs are on their formularies and providers prescribe what is both clinically appropriate and covered by the patient's insurance.

340B harms independent pharmacies.

- 340B savings provide additional reimbursement to independent pharmacies and is one way that we can preserve independent pharmacies in Maine.
- PhRMA is increasingly limiting which pharmacies in the country can buy and dispense their drugs.

Questions & Contacts

QUESTIONS?

For over 30 years, the 340B Drug Pricing 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.

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CONTACT INFORMATION

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