



340B Program: What Legislators Should Know

National Foundation of Women Legislators Conference

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Alkermes

AMGEN

 **astellas**

 **Boehringer
Ingelheim**



 **Biogen**

BIOMARIN

 **Bristol Myers Squibb**

CSL

 **Daiichi-Sankyo**



**EMD
SERONO**

 **GILEAD**
Creating Possible

GSK

Genentech
A Member of the Roche Group



 **IPSEN**
Innovation for patient care

Johnson & Johnson

Lilly

Lundbeck 

 **MERCK**
Be well

 **NOVARTIS**


novo nordisk

 **Otsuka**

 **Pfizer**

 **Sage
Therapeutics**

sanofi

 **Sumitomo Pharma**

 **Takeda**

 **ucb** Inspired by patients.
Driven by science.

340B Program Basics

Congress envisioned 340B as a small safety-net program

What is 340B?

An outpatient drug program administered by the federal government **intended to help vulnerable patients gain better access to medicines** at certain qualifying hospitals and clinics.

Who is eligible to participate in 340B?

340B covered entities are defined in federal law and include **certain qualifying hospitals** (e.g., DSH, children's and rural hospitals) **and safety-net clinics** (e.g., community health centers), known as grantees.

Why was 340B created?

To **address unintended consequences of the 1990 Medicaid drug rebate statute** by reinstating discounts manufacturers had voluntarily provided to certain safety-net clinics and hospitals.

How does 340B work?

Manufacturers are required to sell medicines at a discount to covered entities who Congress envisioned would use the money saved to help patients. Discounts average about 59%.

Unlike Other Federal Programs:

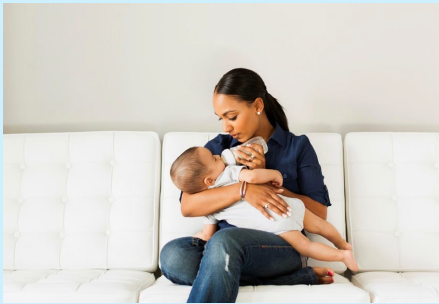
Congress envisioned 340B as a small safety-net program

Medicaid/CHIP

Medicare

VA/DOD/TRICARE

340B



Sales at the 340B Price Have Skyrocketed

2nd

340B is the **second largest prescription drug program**

Larger than Medicare Part B,
Medicaid and VA / Tricare /
DOD

\$54 Billion

Discounted 340B purchases in 2022, 23% higher than in 2021
Hospitals accounted for 87% of program purchases

340B: Was Supposed to Help Patients

Stakeholders in the Unintentional Profit Stream

1

Manufacturers:
fund the 340B
program entirely

2

**Covered
Entities:**
Providers -non-
profit
hospitals/clinics

3

PBMs/Insurers

4

**3rd Party
Administrators/
Data Vendors**

5

**Contract
Pharmacies**

6

Wholesalers

Who Are the 340B Covered Entities?

Unlike other federal drug programs, eligibility is tied to covered entities not patients

Grantees

- Federally Qualified Health Centers
- Community Health Centers
- Migrant Health Centers
- Health Care for the Homeless Centers
- Tribal Facilities and Urban Indian Orgs
- Family Planning Clinics
- Ryan White Clinics
- AIDS Drug Assistance Programs (ADAPs)
- Sexually Transmitted Disease / TB Clinics
- Black Lung Clinics
- Hemophilia Diagnostic Treatment Centers
- Native Hawaiian Health Centers

Hospitals

- Disproportionate Share Hospitals (DSH)
- Children's Hospitals
- Critical Access Hospitals*
- Free Standing Cancer Hospitals*
- Rural Referral Centers*
- Sole Community Hospitals*

**Categories of covered entities added by the ACA*



There is no 340B program requirement that covered entities report how they use 340B profits to help uninsured or low-income patients

Contract Pharmacy: Past and Present

Contract pharmacies were born out of agency guidance and are not mentioned in the 340B law



HRSA stated in **guidance** that it would allow covered entities without their own in-house pharmacy to access 340B discounts through a contract with a single retail pharmacy.

1996



HRSA issues 2010 guidance that allows covered entities to contract with an **unlimited number** of contract pharmacies.
ACA expands 340B hospital eligibility

2010



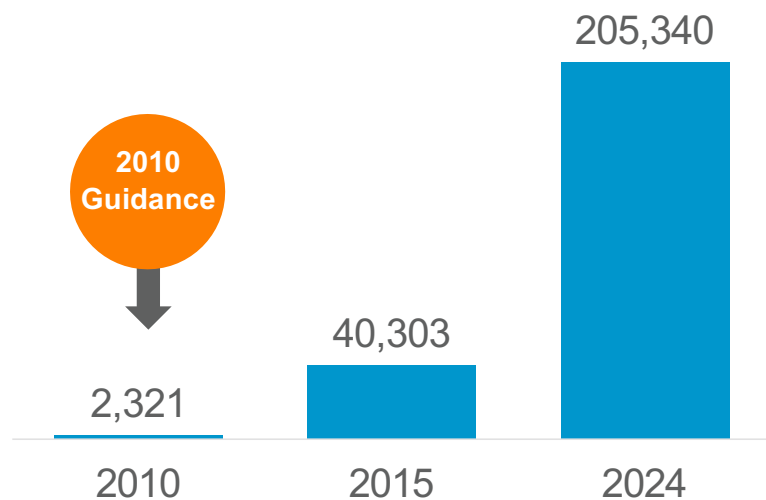
Uptick in Action:

Dec 2020 HHS Contract Pharmacy Advisory Opinion (rescinded)
Contract pharmacy lawsuits in several Circuits
State activity

2020- present

Covered Entities Contract with Pharmacy Chains to Increase Profits

Contract Pharmacy Arrangements

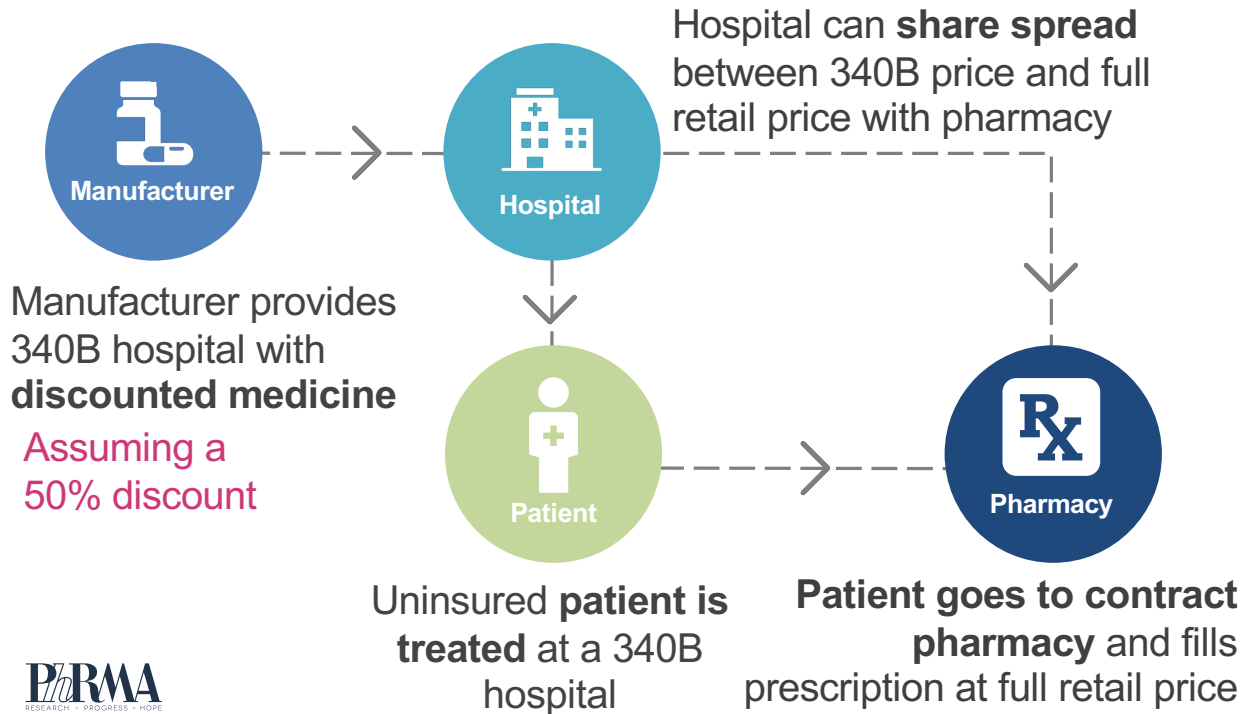


- HRSA allows 340B covered entities to have an **unlimited number of contracts** with pharmacies to dispense 340B medicines
- Currently, **over 33,000 distinct pharmacies** participate in the 340B program, and each one may have arrangements with multiple entities inside and outside their state
- The number of contract pharmacy arrangements has **grown by more than 8,500% since the 2010 guidance**

Case Study: How Hospitals and Pharmacies Profit Off 340B

(Retail Prescription Medicine for Uninsured Patient)

When 340B discounted medicines are shipped to contract pharmacies, the hospital and pharmacy profit while the patient may see no direct benefit from the 340B discount



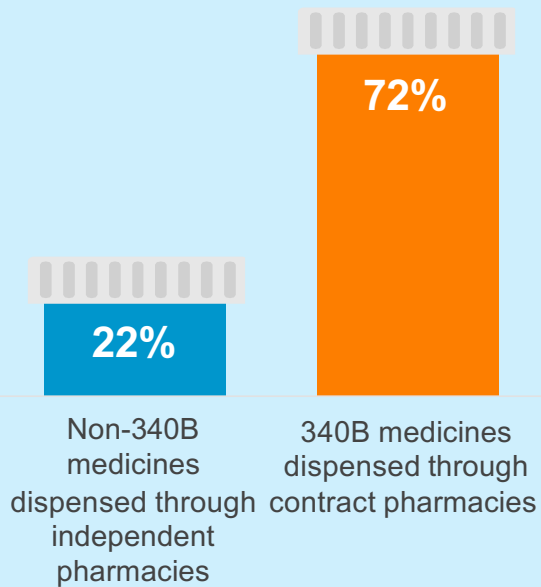
Example assuming \$100 medicine:

-\$50	Discounted 340B purchase price paid by hospital
+\$100	Full retail price paid by uninsured patient
\$50	profit for 340B hospital to share with contract pharmacy

How are profits used?

Pharmacies Have Growing Financial Stake in 340B

Massive Profit Margins



Berkeley Research Group, "For-Profit Pharmacy Participation in the 340B Program," October 2020.

Concentrated Corporate Profits

> 50%



More than half of 340B profits retained by contract pharmacies are **concentrated in four pharmacy companies**

Berkeley Research Group, "For-Profit Pharmacy Participation in the 340B Program," October 2020.

Pharmacy Chains and PBMs Wield Negotiating Power



75% of arrangements are between 340B entities and **five multi-billion-dollar, for-profit, publicly traded pharmacy chains and PBMs**

Drug Channels, "For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market," July 2023

Vertical Integration

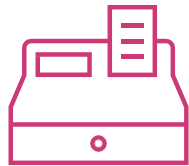


1. Cigna partners with providers via its Cigna Collaborative Care program. However, Cigna does not directly own healthcare providers.
 2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
 3. Since 2020, Prime sources formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
 Source: Drug Channels Institute research; Companies are listed alphabetically by insurer name.

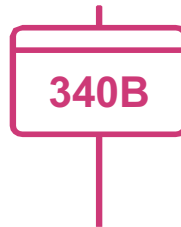
This chart appears as Exhibit 210 in *The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Available at <http://drugch.nl/pharmacy>

Consolidation is Driven by Potential for 340B Profit

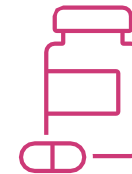
No obligation to invest profits from 340B sales at satellite facilities into underserved communities



**340B CEs
purchase
independent
physician offices**



**They register
those practices
as 340B sites**



**They can then buy
more medicines at
the discounted
340B price**

No Clear Evidence Contract Pharmacy Growth Helps Vulnerable Patients Access 340B Medicines

Growth in Share of 340B Contract Pharmacies in Specific Communities, 2011-2019



“Growth of [pharmacy] contracts with 340B hospitals was less likely in areas with higher uninsured rates and in medically underserved areas.”

Study After Study Raises Concern Patients Aren't Benefiting

340B covered entities must be held more accountable within the program

Evidence Finds
Lack of Improved
Care for Patients
at 340B
Hospitals

New England Journal of Medicine

*“[F]inancial gains for [340B] hospitals have **not been associated with clear evidence of expanded care or lower mortality among low-income patients.**”*

NEJM, “Consequences of the 340B Drug Pricing Program,”
February 2018

American Journal of Managed Care

*“[T]he 340B program has **not been associated with net increases in community benefit spending or outcomes for low-income populations.**”*

AJMC, “340B Drug Pricing Program and Hospital Provision of
Uncompensated Care,” October 2021

Why it Matters: Abuse of 340B Has Real Life Consequences

Recent *New York Times* article presents a vivid and alarming case study

Driving Up Costs

“The program ... allows hospitals to buy drugs from manufacturers at a discount — roughly half the average sales price.

“The hospitals are then allowed to **charge patients’ insurers a much higher price** for the same drugs.”



Reducing Access

340B “was created with the intention that hospitals would reinvest the windfalls into their facilities, improving care for poor patients.

“But Bon Secours ... has been **slashing services at Richmond Community while investing in the city’s wealthier, white neighborhoods ...**”

Contributing to Health Inequities

“Richmond Community ... had closed its I.C.U. in 2017.

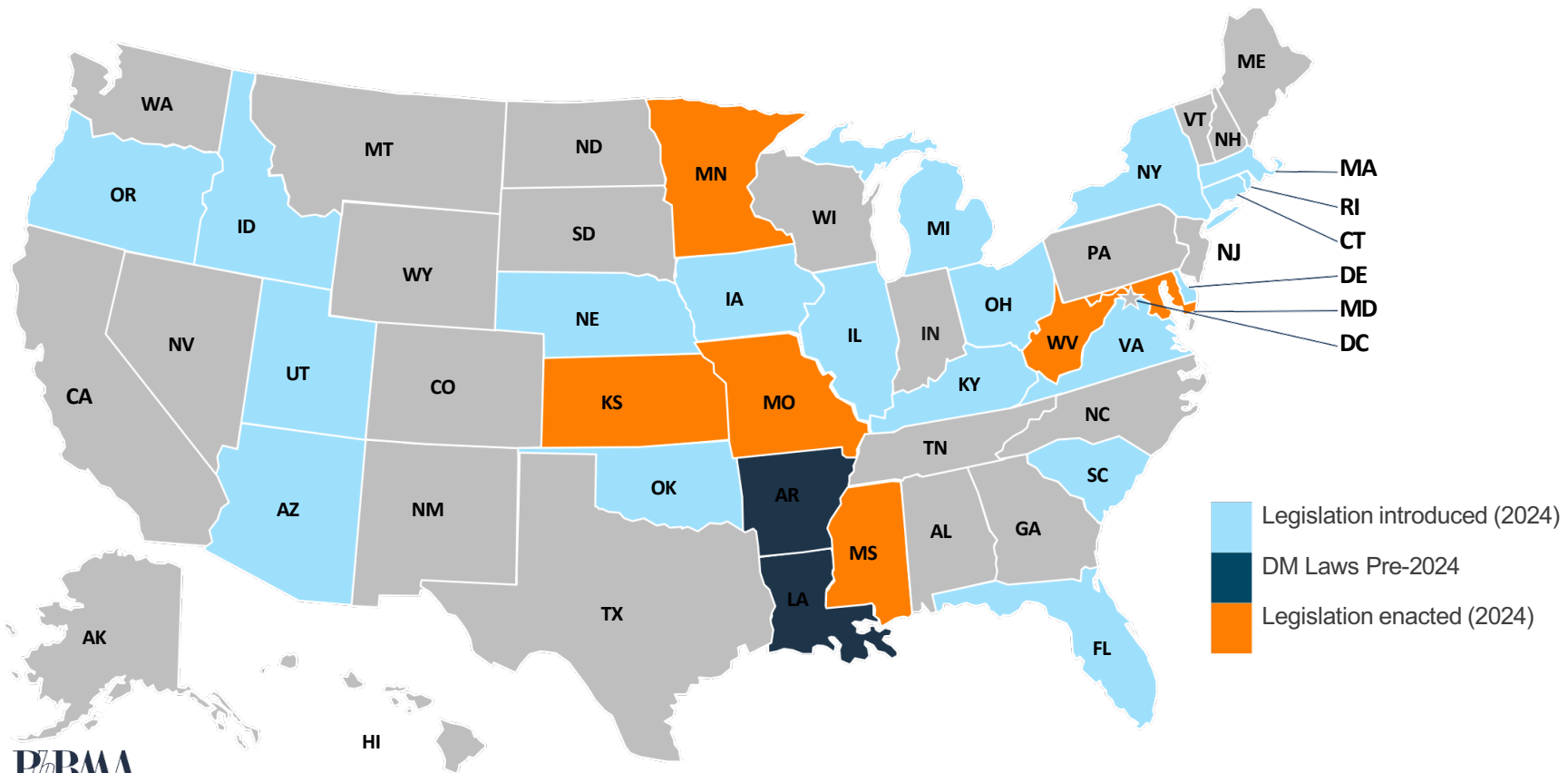
“It took several hours for Mr. Otey to be transported to another hospital... .

“He deteriorated on the way there, and later died of sepsis.”

Evolution: State Legislation

2024 State Legislative Activity: 340B CP Mandate

As of 9/10/2024



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340B is broken and in need of federal reform

The current system does not work for patients

1 340B is not improving access or addressing health inequities

2 PBMs and pharmacies are profiting at the expense of patients

3 340B is growing, but patients are not the ones benefitting

4 340B is driving up patient costs

5 340B is fueling provider consolidation

6 There is no transparency into how manufacturer discounts are used

340B Causes Many Patients to Pay More Out of Pocket

Economists have noted there are market-distorting incentives in 340B

340B is **driving consolidation** in the health care market

GAO and Milliman have cited the incentives to **prescribe more medicines and more expensive medicines** at 340B hospitals

Hospitals buy medicines at discounted 340B rate but then **charge patients a marked up price**

Rapid program growth may be **affecting market prices for prescription medicines**, according to economists

Solution



Solutions: Congress Must Fix 340B

Congress
should fix the
program by:



Making sure the program reaches low-income or otherwise vulnerable patients, lowering their medicine costs.



Ensuring true safety-net providers – the ones serving our nation’s low-income and vulnerable patients – are the ones participating in the program.



Instituting stronger accountability measures to ensure the program is serving patients and our nation’s true safety-net providers.

PhRMA Created the Medicine Assistance Tool, or MAT, To Help Patients Navigate Medicine Affordability

MAT makes it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable.

The Medicine Assistance Tool Includes:

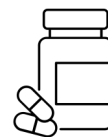
A search engine to connect patients with

900+

assistance programs offered by biopharmaceutical companies, including some free or nearly free options



Resources to help patients navigate their insurance coverage



Links to biopharmaceutical company websites where information about the cost of a prescription medicine is available

QUESTIONS?

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Resources



Key Resources



Congress: 340B needs real reform

Focused on DC, potential federal champions



Who's really benefiting from 340B?

Focused on DC, potential federal champions, state threats where appropriate

Patients deserve better from 340B

Focused on state threats, broad federal influence

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