The 340B program was originally created in 1992 to help safety-net facilities, like clinics and hospitals, that serve a large number of vulnerable or uninsured patients. The program requires pharmaceutical manufacturers to provide steep discounts to these facilities as a condition of their medicines being covered by Medicaid.

The 340B program sought to address unintended consequences of the 1990 Medicaid drug rebate statute by reinstating deep discounts that pharmaceutical manufacturers had voluntarily provided to certain clinics and hospitals treating low-income and/or uninsured patients. Today, however, the 340B program bears little resemblance to what Congress envisioned.

Flawed guidance, historically weak oversight, and lack of transparency have contributed to a 340B program that has more than quadrupled in size since 2014 alone, reaching $38 billion in 340B medicine purchases in 2020. Currently, most of the financial benefits from the 340B program go to large hospital systems, for-profit pharmacies, and other middlemen—not patients relying on the safety net.
How Entities Qualify to Participate in 340B

Unlike government programs designed to provide insurance coverage, patients do not enroll in 340B.

340B DESIGNATION does not apply to patients; instead it applies to the covered entity, which can be a hospital or a clinic (also known as a grantee). The 340B hospital or clinic may claim steep discounts on outpatient medicines dispensed to all patients, whether insured or uninsured.

340B Grantee Eligibility

- Clinics and other entities qualify largely based on the receipt of a federal grant from the Department of Health and Human Services.
- Typically, grants are provided to support care for vulnerable populations.

340B Hospital Eligibility

- Most 340B medicines are sold through nonprofit hospitals that qualify for the 340B program based in part on the share of low-income Medicare and Medicaid patients admitted. This is called the disproportionate share hospital (DSH) metric.
- Congress intended DSH to be a proxy for safety-net hospitals treating a significant number of uninsured patients, but, as Medicaid has expanded, more hospitals qualify for 340B based on the DSH even as hospital charity care and the number of uninsured have declined.³

Sources: MedPAC²; Finegold K et al³
340B Has Shifted Over Time; Now the Majority of Discounts Go to Hospitals

Earlier, grantees represented a larger share of total 340B sales. By 2016, hospitals’ share had increased with disproportionate share hospitals (DSHs) driving the majority of this volume, relative to grantees and other qualifying hospitals.

Share of 340B Sales Volume, 2004 vs 2016

- **2004**
  - Grantees: 51%
  - Hospitals: 49%

- **2016**
  - Grantees: 13%
  - Non-DSH Hospitals: 6%
  - DSH Hospitals: 81%

The Affordable Care Act expanded 340B eligibility to qualifying children’s hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.

Sources: Hatwig C; Mathematica
How 340B Discounts Work in the Commercial Market

CASE STUDY

1. Manufacturer provides 340B hospital with discounted medicine.

2. 340B hospital provides medicines to patients, including those with commercial insurance.

3. Commercial insurer reimburses at full negotiated rate; hospital keeps difference as profit.

Reimbursement for medicine from commercial insurer for $1,000 medicine

$700

+$300

30% coinsurance received from patient

$500

340B purchase price for medicine from manufacturer

$500

Profit for 340B entity

$500

Where does this profit go?

As a result of hospital markups, profits for physician-administered medications at 340B hospitals may be even higher.

Sources: AIR 340B⁴; PhRMA⁷
Hospitals Mark Up 340B Medicines With No Evidence Resulting Revenue Helps Patients

340B hospitals charge commercial insurers and cash-paying or uninsured patients roughly 3.8 times the 340B acquisition cost.\(^8\)

340B hospitals are not required to discount these charges for low-income, uninsured patients.

New England Journal of Medicine Questions Benefit to Patients:

“We found no evidence of hospitals using the surplus monetary resources generated from administering discounted drugs to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality.”

Sunita Desai, PhD, New York University; J. Michael McWilliams, MD, PhD, Harvard University\(^9\)

Sources: Community Oncology Alliance\(^6\); Desai S et al\(^9\)
Most 340B Hospitals Provide Below-Average Levels of Charity Care

Distribution of 340B Hospitals by Level of Charity Care as a Percentage of Operating Costs

65% of 340B DSH hospitals have CHARITY CARE RATES below the 2.9% national average for all hospitals in 2019.

Sources: Avalere Health10; Desai SM et al11

Participation in the 340B Drug Pricing Program has not been associated with increases in hospital-reported uncompensated care provision....”

Sunita M. Desai, PhD, New York University; J. Michael McWilliams, MD, PhD, Harvard University11
340B Growth Has Outpaced Charity Care Provided

The 340B program has grown from $6.9 billion in discounted sales in 2012 to $38.0 billion in discounted sales in 2020. However, charity care for 340B DSH hospitals has remained relatively flat over this time period.

Sources: Drug Channels Institute\textsuperscript{12}; Avalere Health\textsuperscript{13}
340B Has Grown Dramatically Since 1992

340B is now the 2ND LARGEST federal prescription DRUG PROGRAM, behind only Medicare Part D and exceeding Medicare Part B, Medicaid, and VA/Tricare/Department of Defense. In 2020, discounted 340B purchases amounted to $38 BILLION, 27% higher than in 2019.

More than 40%+ 2 out of every 5 HOSPITALS in the United States PARTICIPATE in the 340B program, even though it was intended to be a small program, with only 45 hospitals participating in 1992.

Sources: BRG14; MedPAC15, BRG16; Drug Channels Institute17
Today’s 340B Program Diverges From What Congress Enacted

340B was intended as a small safety-net program. However, the profit incentives created by the program’s vague guidance and lax oversight have fueled rapid expansion in recent years—particularly by large hospital systems—making the program unrecognizable in both size and scope from what Congress envisioned almost 30 years ago.

Sources: BRG18,19; Drug Channels Institute20

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340B Hospital Participation\(^{18}\)

<table>
<thead>
<tr>
<th>Year</th>
<th>Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1992</td>
<td>45</td>
</tr>
<tr>
<td>2000</td>
<td>108</td>
</tr>
<tr>
<td>2010</td>
<td>1,191</td>
</tr>
<tr>
<td>2020</td>
<td>2,660</td>
</tr>
</tbody>
</table>

Sales at 340B Price\(^{19,20}\)

THE PROGRAM HAS INCREASED 4X SINCE 2014 ALONE.

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>$5B</td>
</tr>
<tr>
<td>2013</td>
<td>$10B</td>
</tr>
<tr>
<td>2014</td>
<td>$15B</td>
</tr>
<tr>
<td>2015</td>
<td>$20B</td>
</tr>
<tr>
<td>2016</td>
<td>$25B</td>
</tr>
<tr>
<td>2017</td>
<td>$30B</td>
</tr>
<tr>
<td>2018</td>
<td>$35B</td>
</tr>
<tr>
<td>2019</td>
<td>$40B</td>
</tr>
<tr>
<td>2020</td>
<td>$45B</td>
</tr>
</tbody>
</table>
340B Profits Incentivize Hospital Consolidation and Drive Costs for Patients

340B hospitals’ ability to profit from the program has created incentives for them to purchase independent physician practices to have those practices qualify for 340B discounts. Many economists have concluded that this leads to more consolidation that raises prices for patients and the health care system.

Source: BRG21; Parente S et al22

Site of Care for All Drug Therapies Reimbursed in Medicare Part B (2008-2017)21

[The 340B program] will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings. . . .”

Stephen Parente, PhD, MPH, MS, University of Minnesota22

Sources: BRG21; Parente S et al22
Broken Incentives Encourage 340B Hospitals to Use More Expensive Medicines

Evidence suggests profit incentives are leading to higher spending on outpatient medicines at 340B hospitals as compared with non-340B hospitals. One study found “per patient pharmacy spend at 340B DSH hospitals is almost three times the spend of non-340B hospitals.”

Average per Patient Spend on Outpatient Medicines

- **340B DSH**: $457 billion
- **Non-340B DSH**: $159 billion

2015 commercial data

[The 340B program] passes profound discounts through to 340B entities. They will make 30%, 40%, maybe 50%—double their money, in some cases—on drugs, which is a powerful incentive to use more expensive drugs.”

*Peter Bach, MD*

Sources: Milliman²³; Bach P et al²⁴
340B Causes Many Patients to Pay More Out of Pocket

**CONSOLIDATION**
in the health care market, partially driven by perverse incentives in 340B, causes costs to go up for patients.\(^\text{25}\)

**INCENTIVES**
exist at 340B hospitals to prescribe both more medicines and more expensive medicines.\(^\text{26}\)

**RAPID PROGRAM GROWTH**
may be affecting market prices for prescription medicines.\(^\text{25}\)

Research reported in the *New England Journal of Medicine* found:

)[T]he [340B] discounts—which range from 20% to 50%—only strengthen the incentives for hospitals to supply drugs to patients who have generous insurance coverage.”

Sunita Desai, PhD, New York University; J. Michael McWilliams, MD, PhD, Harvard University\(^\text{27}\)

Sources: Conti R et al\(^\text{25}\); Milliman\(^\text{26}\); Desai S et al\(^\text{27}\)
Contract Pharmacies: Past and Present

The 2010 contract pharmacy policy has allowed for-profit corporations to expand the 340B program with no clear benefit to patients. Currently, hospitals have created expansive networks of contract pharmacies, where they can obtain the 340B discounts and share in the profits but do not have to share any savings with patients.

1996

The Health Resources and Services Administration (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.

2010

The contract pharmacy policy was dramatically expanded under HRSA’s 2010 contract pharmacy guidance to allow all 340B entities to have an unlimited number of contract pharmacy arrangements.

Source: GAO28
Contract Pharmacies Do Not Always Help Patients Afford Their Medicines

What Can Happen When 340B Medicines Are Dispensed Through Contract Pharmacy Arrangements:

Uninsured patient gets sick.
Uninsured patient gets treated at a 340B hospital.
Patient goes to 340B contract pharmacy and fills prescription at full retail price ($100).
Hospital gets $50 back from drug manufacturer, which it shares with the pharmacy.

The hospital and pharmacy profit, while the patient may see no direct benefit from the 340B discount.

Source: AIR 340B
340B Contract Pharmacy Participation Has Increased Dramatically

The number of contract pharmacy arrangements has grown by more than 4,000% since the 2010 guidance. Currently, nearly 30,000 distinct pharmacies participate in the 340B program, and each one may have arrangements with multiple entities.

*Source: BRG*

*A contract pharmacy may have multiple contracts with multiple 340B hospitals.*
For-Profit Pharmacies Have a Growing Financial Stake in the 340B Program

Although the 340B program was originally limited to safety-net providers, the current contract pharmacy guidance has given for-profit and vertically integrated pharmacies a big role in the program.

- Nearly 75% of contract pharmacies are chain pharmacies.³¹
- Nearly 60% of contract pharmacies are represented by CVS, Walgreens, Walmart, Rite-Aid, and Kroger.³¹
- Nearly 20% of contract pharmacy arrangements are between 340B entities and the 3 largest PBM-owned specialty and mail pharmacies.³²

 Sources: GAO³¹; Drug Channels Institute³²

PBM = pharmacy benefits management
# For-Profit Middlemen Wield Strong Negotiating Power

Although the 340B program was originally limited to safety-net providers, for-profit and vertically integrated pharmacies are increasingly profiting from the program. Specialty and mail-order pharmacies owned by PBMs also represent the fastest growing share of the 340B market, raising questions about whether profits from 340B could impact coverage decisions.\(^{33}\)

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### Vertical Integration of 340B Contract Pharmacies and Affiliates\(^ {34*}\)

<table>
<thead>
<tr>
<th>PHARMACY (Retail, mail order, and/or specialty)</th>
<th>CVS Caremark</th>
<th>Accredo</th>
<th>Walgreens</th>
<th>Optum Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBM</td>
<td>CVS Caremark</td>
<td>Express Scripts</td>
<td>OptumRx</td>
<td></td>
</tr>
<tr>
<td>HEALTH PLAN</td>
<td>Aetna</td>
<td>Cigna</td>
<td>United Healthcare</td>
<td></td>
</tr>
<tr>
<td>THIRD-PARTY 340B SERVICES FIRM</td>
<td>Wellpartner</td>
<td>Verity Solutions</td>
<td>340B Complete Shields Health Solution</td>
<td></td>
</tr>
</tbody>
</table>

*Illustrative example of 340B relationships between companies, not meant to be comprehensive

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More than half of the 340B profits retained by contract pharmacies are concentrated in just 4 pharmacy providers, many of which are affiliated with a health plan, PBM, and/or third-party 340B services firm. This provides dominant bargaining power and raises anticompetitive concerns arising from financial interests due to their contract pharmacies’ participation in 340B. These corporations leverage their own contract pharmacies to maximize their potential 340B profits to drive program growth.

Sources: Drug Channels Institute\(^ {33}\); BRG\(^ {34}\)
340B Program Profitable for Contract Pharmacies, Not Helping Patients

Despite 4,000% growth in contract pharmacy participation in the program, there is no clear evidence 340B hospitals and their contract pharmacies always or even usually help patients in need access medicines.

Massive Profit Margin

| Non-340B medicines commonly dispensed through independent pharmacies | 22% |
| 340B medicines commonly dispensed through contract pharmacies | 72% |

Significant Gross Profits

$13 BILLION generated in estimated gross profits in 2018 for 340B-covered entities and their contract pharmacies from 340B prescriptions filled at contract pharmacies.

Nearly half of the top-20 companies on the Fortune 500 list generate revenue from 340B, whether as a contract pharmacy, third-party administrator, health plan, PBM, or wholesaler.

Source: BRG

Medicines in 340B
Nearly Two-Thirds of 340B Hospitals Do Not Provide Discounts to Low-Income, Uninsured Patients at Contract Pharmacies

Both the Office of Inspector General (OIG) and the Government Accountability Office (GAO) found that less than half of hospitals passed 340B discounts to low-income, uninsured patients at contract pharmacies.

“Neither the 340B statute nor HRSA guidance addresses whether covered entities must offer the discounted 340B price to uninsured patients; however, if covered entities do not, uninsured patients pay the full non-340B price....”

Office of Inspector General

Sources: GAO; OIG

Share of Hospitals That Reported Providing Discounts to Low-Income, Uninsured Patients on 340B Medicines Dispensed at Contract Pharmacies

- 57% Do not provide discounts
- 25% Provide discounts at all contract pharmacies
- 18% Provide discounts at some contract pharmacies
Government Watchdogs Note Concerns With Contract Pharmacies and Program Integrity

OIG (2014)

Contract Pharmacy Arrangements in the 340B Program

- Contract pharmacy arrangements make 340B compliance more difficult for covered entities in terms of diversion and duplicate discounts.
- Without adequate oversight, the 340B program is exposed to hazards due to the complexity created from contract pharmacy agreements.

GAO (2018)

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

- Deficiencies in HRSA’s oversight make it impossible to verify contract pharmacies’ compliance with 340B program requirements.
- Contract pharmacies often make more money on brand medicines than they do on generics.

Sources: OIG; GAO
Program Integrity and Compliance Concerns Extend Beyond Contract Pharmacies

GAO analysis found that 73% of Health Resources and Services Administration’s (HRSA) audits resulted in at least 1 finding of noncompliance with 340B requirements. Additionally, GAO found it is likely that private hospitals participating in 340B are not meeting basic standards for program eligibility.

<table>
<thead>
<tr>
<th>340B program findings of noncompliance:</th>
<th>Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELIGIBILITY OF COVERED ENTITIES</td>
<td>561</td>
</tr>
<tr>
<td>Failure to maintain eligibility-related requirements</td>
<td></td>
</tr>
<tr>
<td>DIVERSION OF 340B MEDICINES TO INELIGIBLE PATIENTS</td>
<td>546</td>
</tr>
<tr>
<td>340B medicines distributed to individuals who are not eligible patients of a covered entity</td>
<td></td>
</tr>
<tr>
<td>DUPLICATE DISCOUNTS</td>
<td>429</td>
</tr>
<tr>
<td>Medicines that may have been subject to both the 340B price and a Medicaid rebate</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>1,536</td>
</tr>
</tbody>
</table>

Results may underestimate noncompliance because, starting in fall 2019, the GAO was told by HRSA that “it would no longer issue [audit] findings based solely on noncompliance with guidance.”

Source: GAO
The Lack of Definition of a 340B Patient Makes It Difficult to Ensure Patients Directly Benefit From Discounts

Covered entities are only permitted to use 340B discounts for individuals who meet the definition of a patient under the program, but **HRSA guidance fails to clearly define who is a 340B patient.**

There is no way for a patient to know if a prescription qualifies as a 340B-discounted medicine.

Currently, 340B patients are often identified by covered entities after they’ve picked up their prescriptions, so patients can’t directly benefit.

HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency… did not issue diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance because the 340B statute does not provide criteria for determining patient eligibility.”

**Government Accountability Office**

[There is] a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements.”

**Office of Inspector General**

Sources: GAO⁴¹; OIG⁴²
Government Oversight Raises Concerns About HRSA’s Management of 340B

**JULY 2017:**
House Energy and Commerce Committee Hearing

There are a number of critical issues that remain unresolved [with the 340B program]…Continued lack of specificity and program guidance, most notably the definition of a patient and hospital eligibility criteria.”

Government Accountability Office

**MAY 2018:**
Senate Health, Education, Labor, and Pensions Committee Hearing

[T]he steps HRSA has taken do not fully address the long-standing challenges identified by OIG. As such, OIG continues to recommend improving the 340B program by increasing transparency and clarifying program rules.”

Office of Inspector General

**JANUARY 2020:**
Report to Congressional Requesters

Hospital participation in the 340B Program, and hospital purchases of discounted drugs through the 340B Program, has risen rapidly over time. However, HRSA’s current processes and procedures do not provide reasonable assurance that nongovernmental hospitals seeking to participate and benefit from the 340B Program meet the program’s eligibility requirements.”

Government Accountability Office

Sources: GAO; OIG; GAO
Efforts to Get 340B Back on Track Must Tackle These Areas

- Realigning 340B with its original mission as a true safety-net program that puts patients first
- Protecting the program from further abuse by covered entities, pharmacies, and other middlemen
- Increasing transparency and establishing clearer rules needed to ensure accountability in the program
Notes and Sources


10. Avalere Health analysis for PhRMA of FY2019 Medicare cost reports submitted by 3,209 short-term acute care hospitals (STACHs). Of those, 1,128 hospitals were participating in 340B as a DSH entity for a full or a portion of their cost reporting period, based on the enrollment and termination dates in the Office of Pharmacy Affairs (OPA) 340B database (https://340bopais.hrsa.gov), and submitted 2019 Medicare cost report data.


12. Drug Channels Institute analysis for PhRMA of data from the Health Resources and Services Administration (HRSA).


