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Medicines in 340B

SEPTEMBER 2022

INTRODUCTION

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 $44 billion in 340B medicine purchases in 2021.[1] 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.

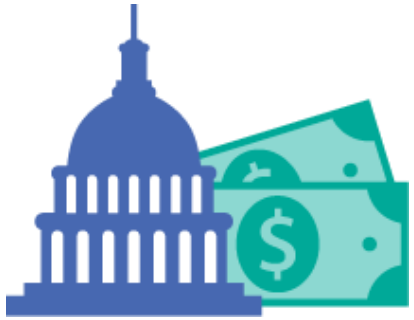
1. Fein AJ; Drug Channels Institute. The 340B Program climbed to $44 billion in 2021—with hospitals grabbing most of the money. Published August 2022. Accessed August 2022. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

How Entities Qualify to Participate in 340B

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

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.[2]

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**).

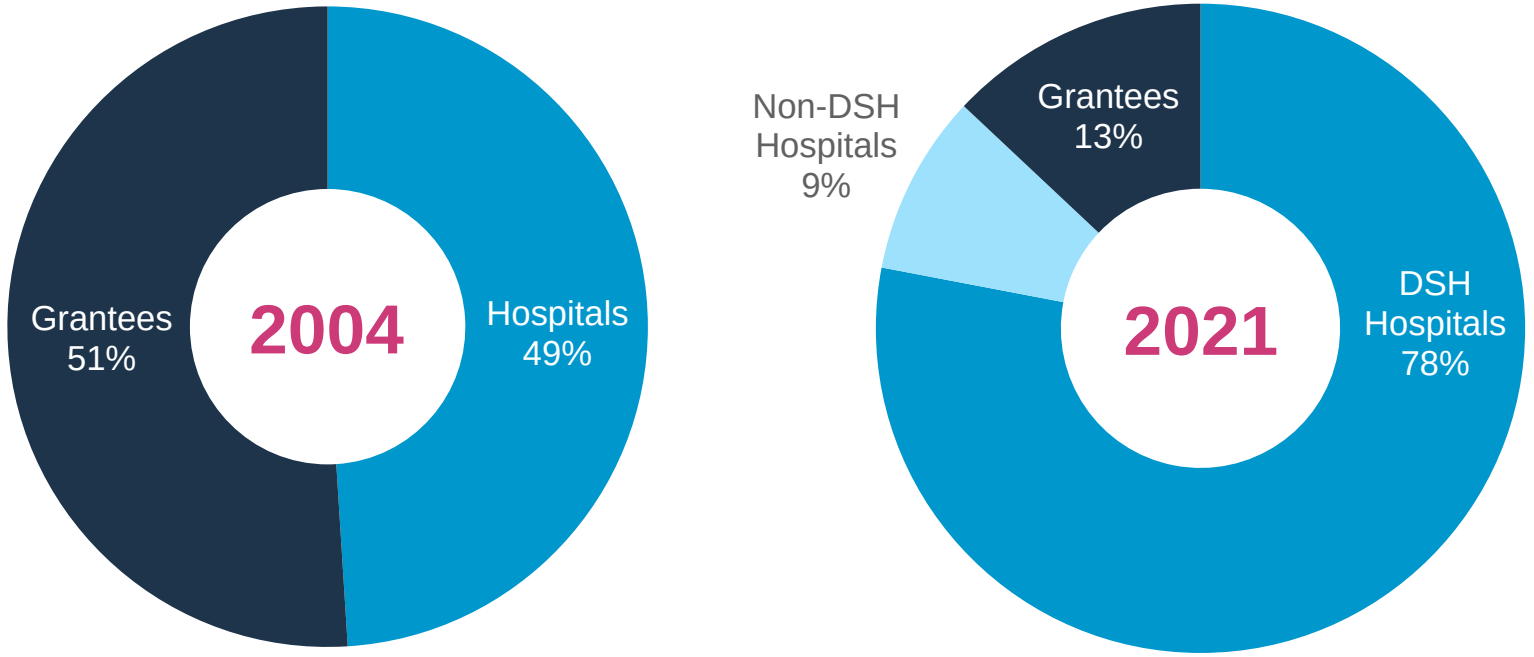
The 340B hospital or clinic may claim steep discounts on outpatient medicines dispensed to all patients, whether insured or uninsured.

1. Medicare Payment Advisory Commission (MedPAC). Report to the Congress: overview of the 340B drug pricing program. Published May 2015. Accessed May 2021. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf
2. Finegold K, Conmy A, Chu RC et al; Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation Office of Health Policy. Issue brief: trends in the US uninsured population, 2010-2020. Published February 2021. Accessed November 2021. https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//198861/trends-in-the-us-uninsured.pdf

340B Has Shifted Over Time; Now the Majority of Discounts Go to Hospitals

Earlier, grantees represented a larger share of total 340B sales. Today, hospitals' share has increased significantly with disproportionate share hospitals (DSHs) driving the majority of this volume, relative to grantees and other qualifying hospitals.

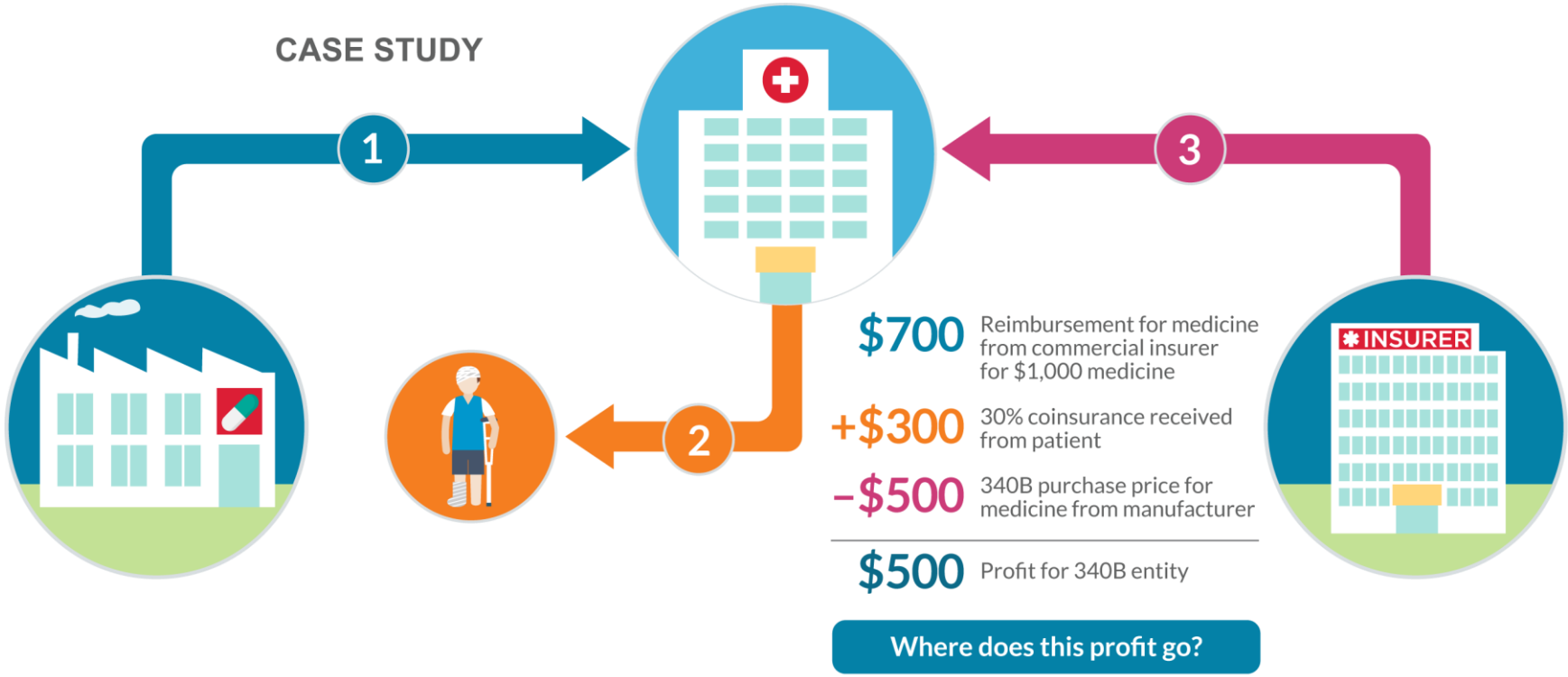
Share of 340B Sales Volume, 2004 vs 2021[1,2]



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.

1. Fein AJ; Drug Channels Institute. The 340B Program climbed to $44 billion in 2021—with hospitals grabbing most of the money. Published August 2022. Accessed August 2022. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html
2. Schmitz R, Limpa-Amara S, Milliner-Waddell J et al; Mathematica. The PHS 340B drug pricing program: results of a survey of eligible entities. August 2004 Apexus, Summer 2018. Accessed November 2021. https://www.researchgate.net/publication/254430113_The_PHS_340B_Drug_Pricing_Program_Results_of_a_Survey_of_Eligible_Entities_Cambridge_MA_Mathematica_Policy_Research

How 340B Discounts Work in the Commercial Market



1. Manufacturer provides 340B hospital with discounted retail medicine.
2. 340B hospital provides retail medicines to patients, including those with commercial insurance.
3. Commercial insurer reimburses at full negotiated rate; hospital keeps difference as profit.

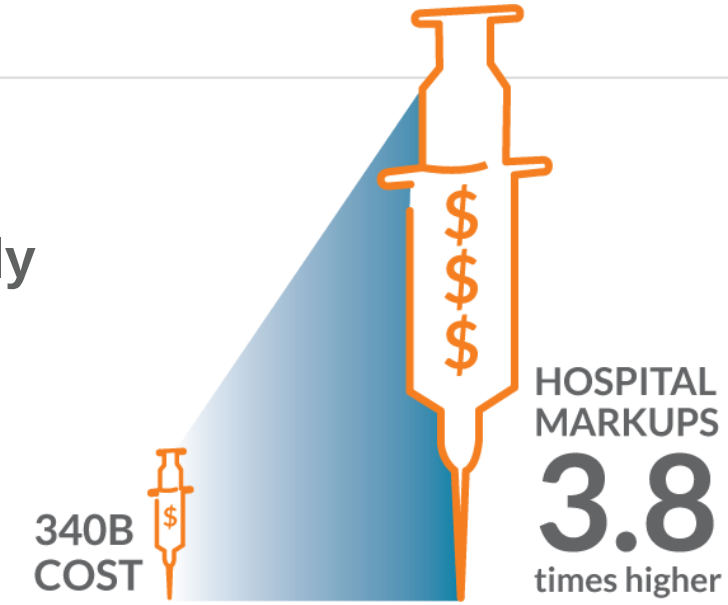
As a result of hospital markups, profits for physician-administered medications at 340B hospitals may be even higher.

1. Alliance for Integrity and Reform of 340B (AIR 340B). Left behind: an analysis of charity care provided by hospitals enrolled in the 340B discount program. Published November 2019. Accessed April 2021. https://340breform.org/wp-content/uploads/2021/04/AIR340_LeftBehind-v6.pdf
2. Pharmaceutical Research and Manufacturers of America (PhRMA). Follow the dollar part II: understanding the cost of brand medicines administered to commercially insured patients in hospital outpatient departments. February 2021. Accessed April 2021. https://www.phrma.org/en/Report/Follow-the-Dollar-Part-2

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.[1]

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

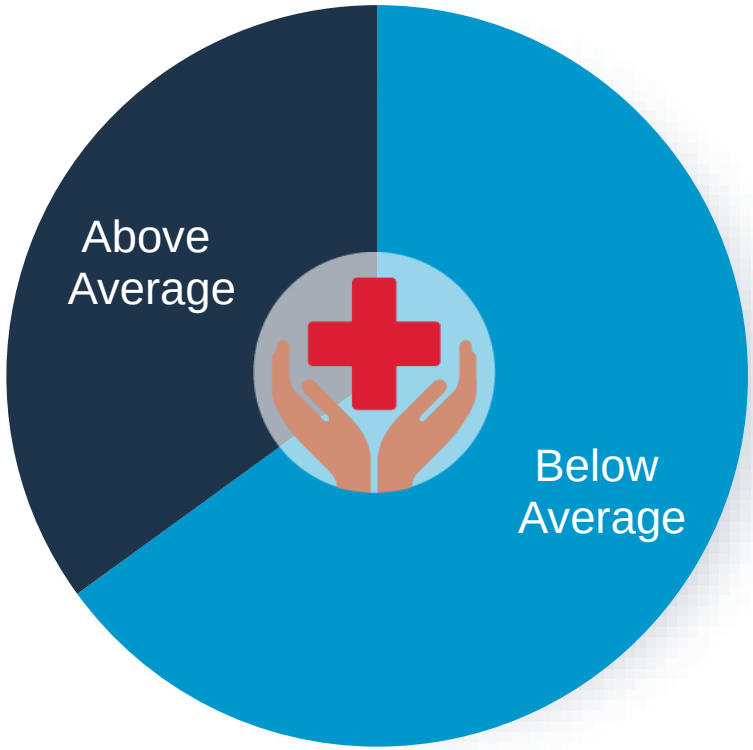
Sunita Desai, PhD, New York University; J. Michael McWilliams, MD, PhD, Harvard University[2]

1. Gal A; Community Oncology Alliance. Examining hospital price transparency, drug profits, & the 340B program. Published September 2021. Accessed November 2021. https://communityoncology.org/wp-content/uploads/2021/09/Moto-COA-340B_Hospital_Markups_Report.pdf
2. Desai S, McWilliams JM. Consequences of the 340B drug pricing program. *N Engl J Med.* 2018;378:539-548. doi:10.1056/NEJMsa1706475

Most 340B Hospitals Provide Below-Average Levels of Charity Care

Less than one third (29%) of hospitals accounted for 80% of charity care provided by all 340B DSH hospitals in 2019.

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.

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

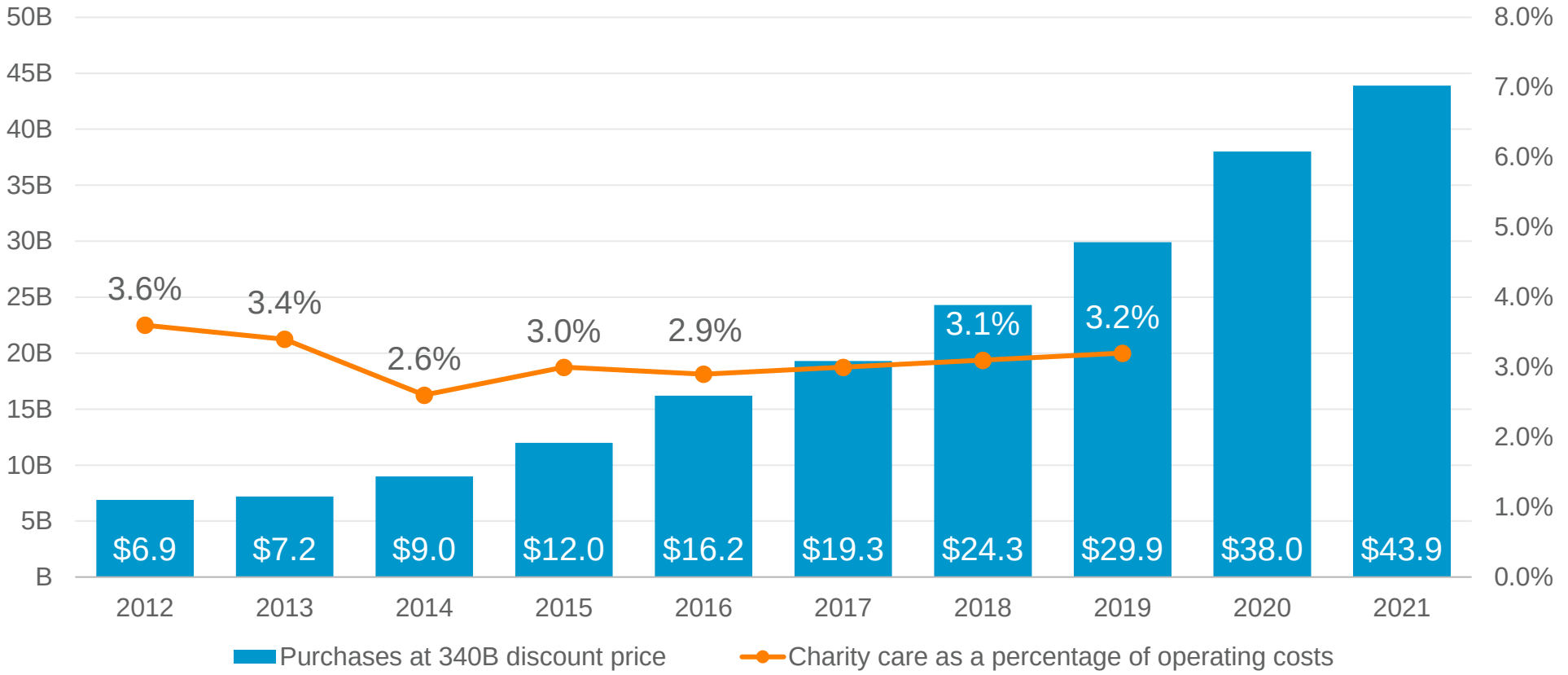
Sunita M. Desai, PhD, New York University; J. Michael McWilliams, MD, PhD, Harvard University[2]

1. AIR340B. Left behind: An analysis of charity care provided by hospitals enrolled in the 340B Drug Pricing Program. Published February 2022. https://340breform.org/wp-content/uploads/2022/02/AIR340B_LeftBehind_2022.pdf
2. Desai SM, McWilliams JM. 340B Drug Pricing Program and hospital provision of uncompensated care. *Am J Manag Care.* 2021;27(10):432-437. doi:10.37765/ajmc.2021.88761

340B Growth Has Outpaced Charity Care Provided

The 340B program has grown from $6.9 billion in discounted sales in 2012 to nearly $44 billion in discounted sales in 2021.[1] However, charity care for 340B DSH hospitals has remained relatively flat over this time period.

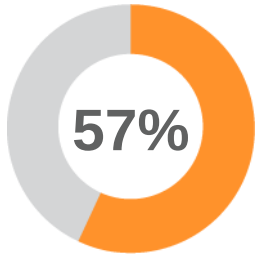
340B Sales Growth[2] vs 340B DSH Charity Care[3]



1. Fein AJ; Drug Channels Institute. The 340B Program climbed to $44 billion in 2021—with hospitals grabbing most of the money. Published August 2022. Accessed August 2022. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html
2. Drug Channels Institute analysis for PhRMA of data from the Health Resources and Services Administration (HRSA).
3. Avalere Health analysis for PhRMA of cost report data from the Centers for Medicare & Medicaid Services.

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 TRICARE/ Department of Defense.[1]



More than **3 out of every 5 HOSPITALS in the United States PARTICIPATE** in the 340B program,[2] even though it was intended to be a small program, with only 45 hospitals participating in 1992.[3]

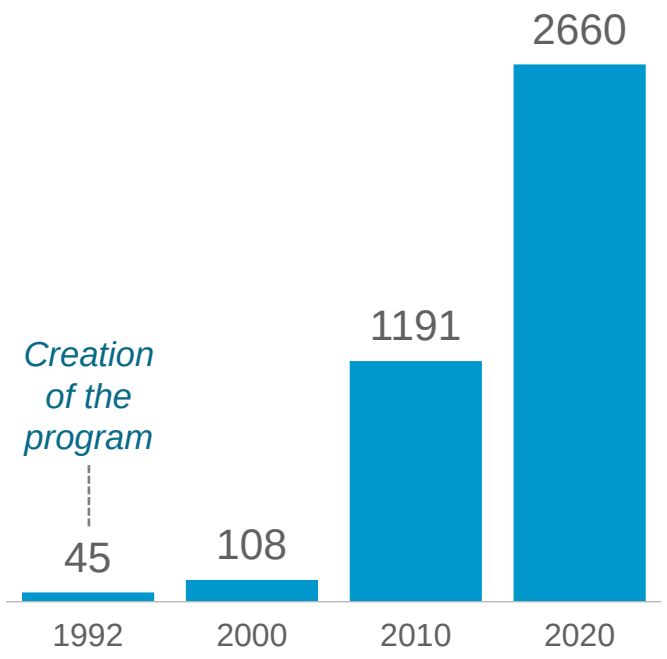
In 2021, discounted 340B purchases amounted to **$44 BILLION,** **16% higher** than in 2021.[4]

1. Blalock E; BRG. Measuring the relative size of the 340B program: 2020 update. Published June 2022. Accessed June 2022. https://www.thinkbrg.com/insights/publications/measuring-relative-size-340b-program-2020-update/
2. MedPAC. Report to the Congress: Medicare and the health care delivery system. Published June 2022. Accessed June 2022. https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_SEC.pdf
3. BRG analysis of HRSA Office of Pharmacy Affairs (OPA) 340B Database. https://340bopais.hrsa.gov
4. Fein AJ; Drug Channels Institute. The 340B Program climbed to $44 billion in 2021—with hospitals grabbing most of the money. Published August 2022. Accessed August 2022. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

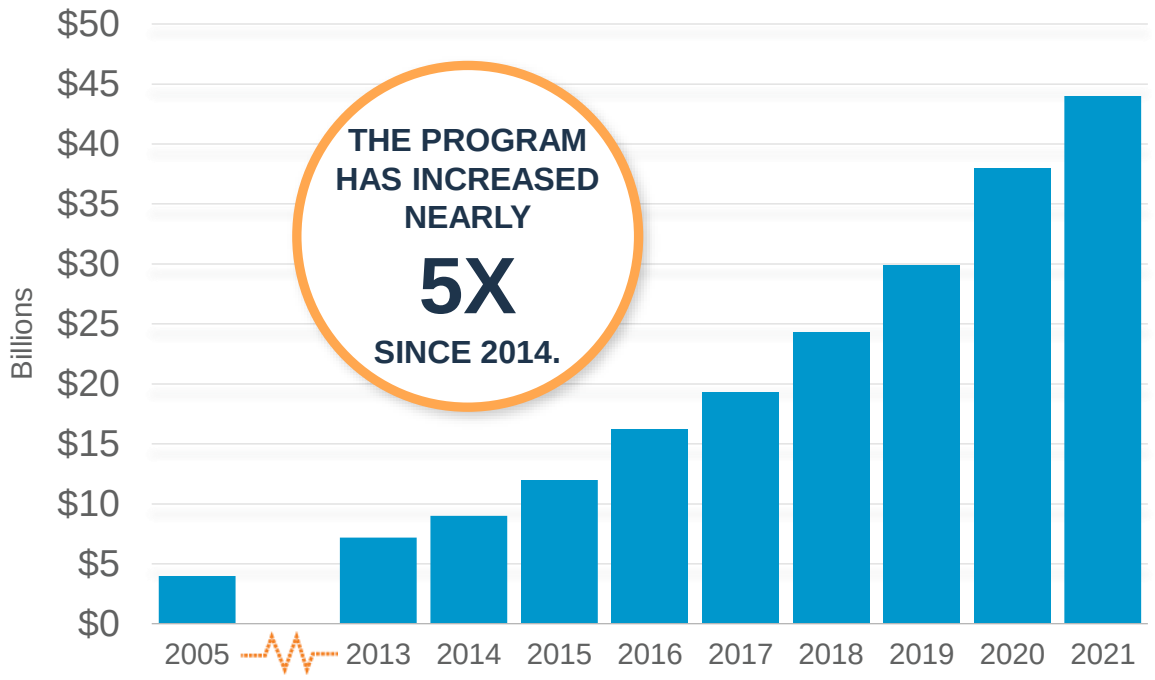
Today's 340B Program Diverges From What Congress Enacted

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.

340B Hospital Participation[1]



Sales at 340B Price[2-4]

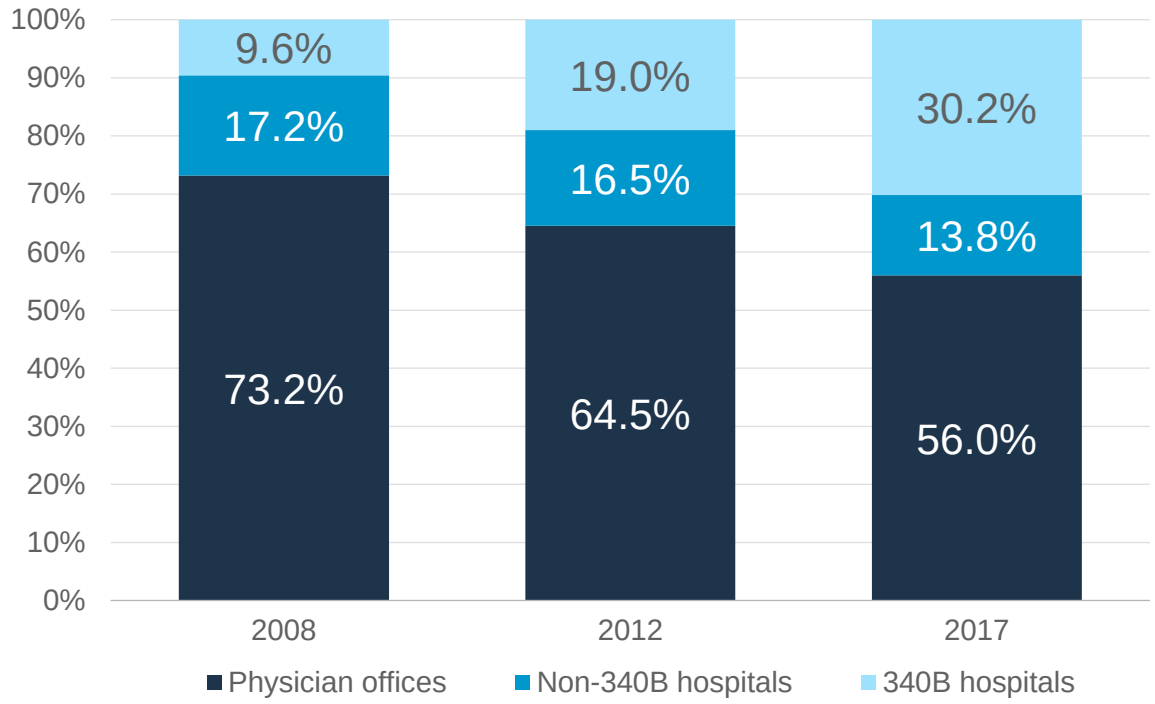


1. BRG analysis of HRSA OPA 340B Database. https://340bopais.hrsa.gov
2. BRG for PhRMA. Presented at 8th annual oncology economics summit estimating the impact of recent legislation on future growth in the 340B program. February 21-22, 2012. Accessed November 2021. http://www.conferagroup.com/documents/Agenda-2012OncologyEconomicsSummit.pdf
3. Fein AJ; Drug Channels Institute. The 340B program soared to $38 billion in 2020—up 27% vs 2019. Published June 2021. Accessed July 2021. https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html
4. Fein AJ; Drug Channels Institute. The 340B Program climbed to $44 billion in 2021—with hospitals grabbing most of the money. Published August 2022. Accessed August 2022. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

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.

Site of Care for All Drug Therapies Reimbursed in Medicare Part B (2008-2017)[1]



1. Blalock E; BRG. Site-of-care shift for physician-administered drug therapies: update. Published March 2019. Accessed December 2020. https://www.thinkbrg.com/insights/publications/site-of-care-shift-for-physician-administered-drug-therapies-update
2. Parente S, Ramlet M. Unprecedented growth, questionable policy: the 340B drug program. Carlson School of Management, University of Minnesota. Published 2014. Accessed May 2020. http://carlsonschool.umn.edu/sites/carlsonschool.umn.edu/files/inline-files/340BMinnesotaWhitePaper%20%281%29.pdf

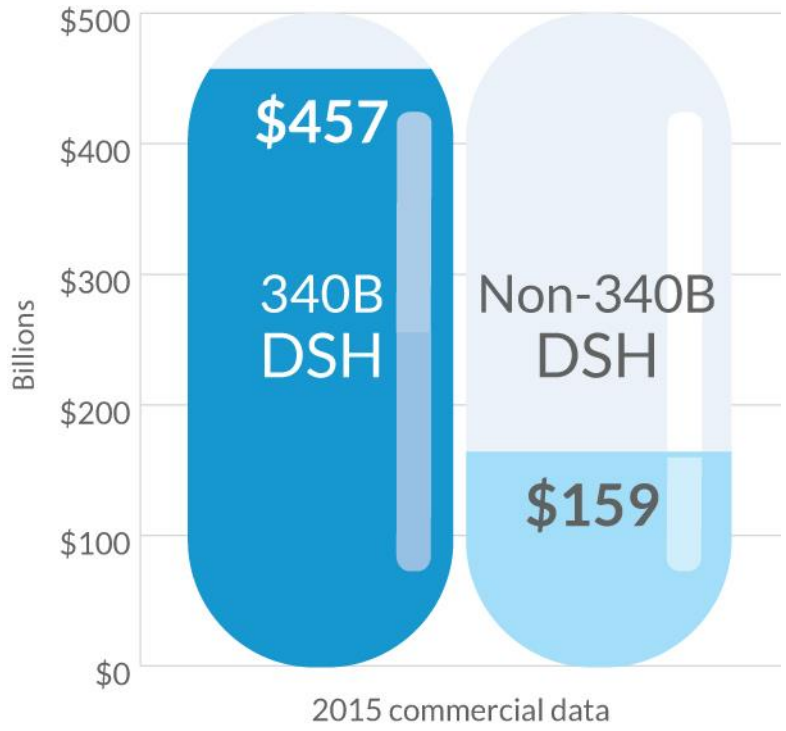
[The 340B program] will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings. . . .”

Stephen Parente, PhD, MPH, MS, University of Minnesota[2]

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.”[1]

Average per Patient Spend on Outpatient Medicines[2]

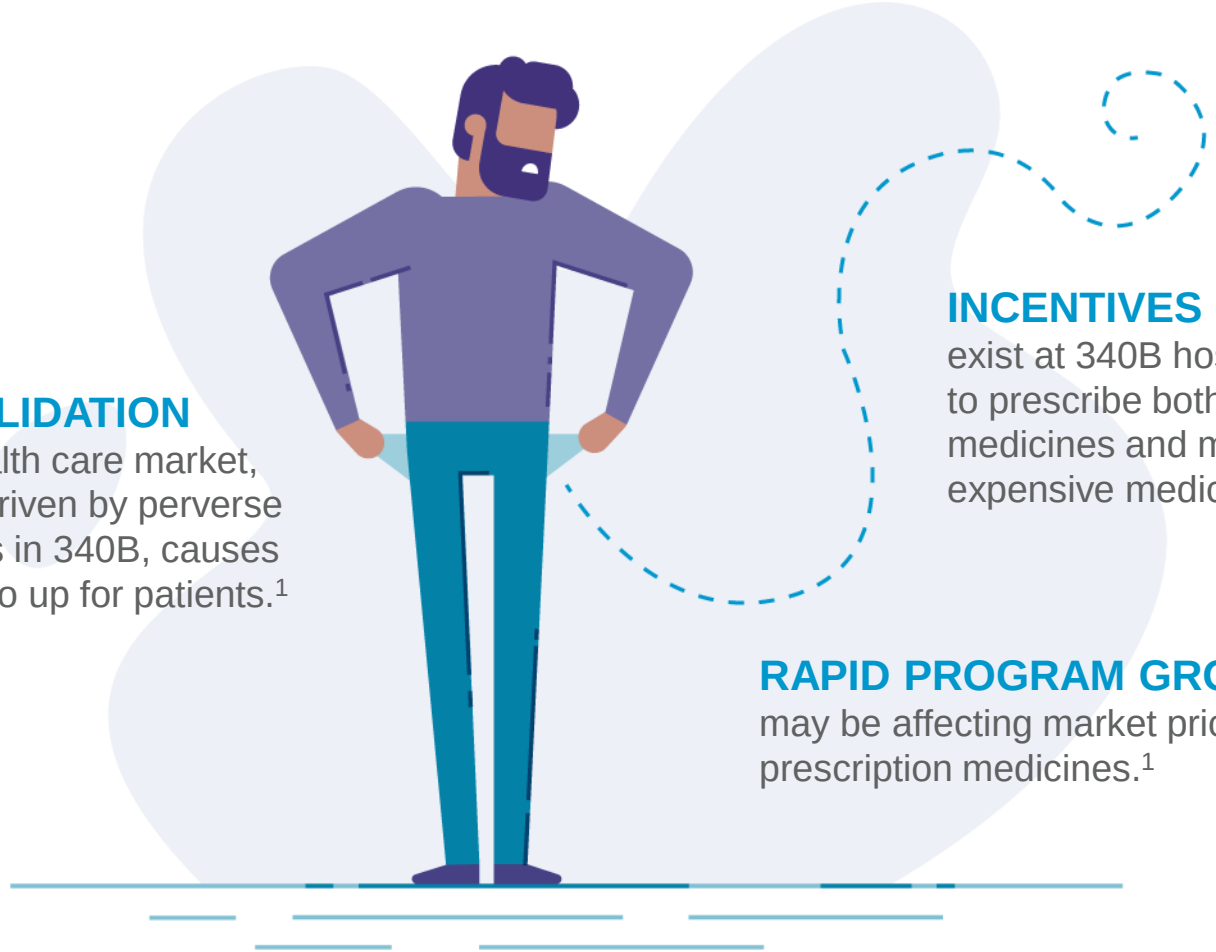


[The 340B program] passes profound discounts through to 340B entities. They will make 30%, 40%, maybe 50%—double their money, in some cases—on drugs, which is a powerful incentive to use more expensive drugs.”

Peter Bach, MD[2]

1. Hunter MT, Gomberg J, Kim C; Milliman. Commercial payers spend more on hospital outpatient drugs at 340B participating hospitals. Published March 2018. Accessed June 2020. https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2018/commercial-payers-spend-more-hospital-outpatient-drugs-340b-hospitals.ashx
2. Bach PB, Miller G; Medscape. Discounted drugs for profit: Peter Bach, MD, on the 340B Program. Published December 2014. Accessed June 2020. https://www.medscape.com/viewarticle/835747

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.[1]

INCENTIVES
exist at 340B hospitals to prescribe both more medicines and more expensive medicines.[2]

RAPID PROGRAM GROWTH
may be affecting market prices for prescription medicines.[1]

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."

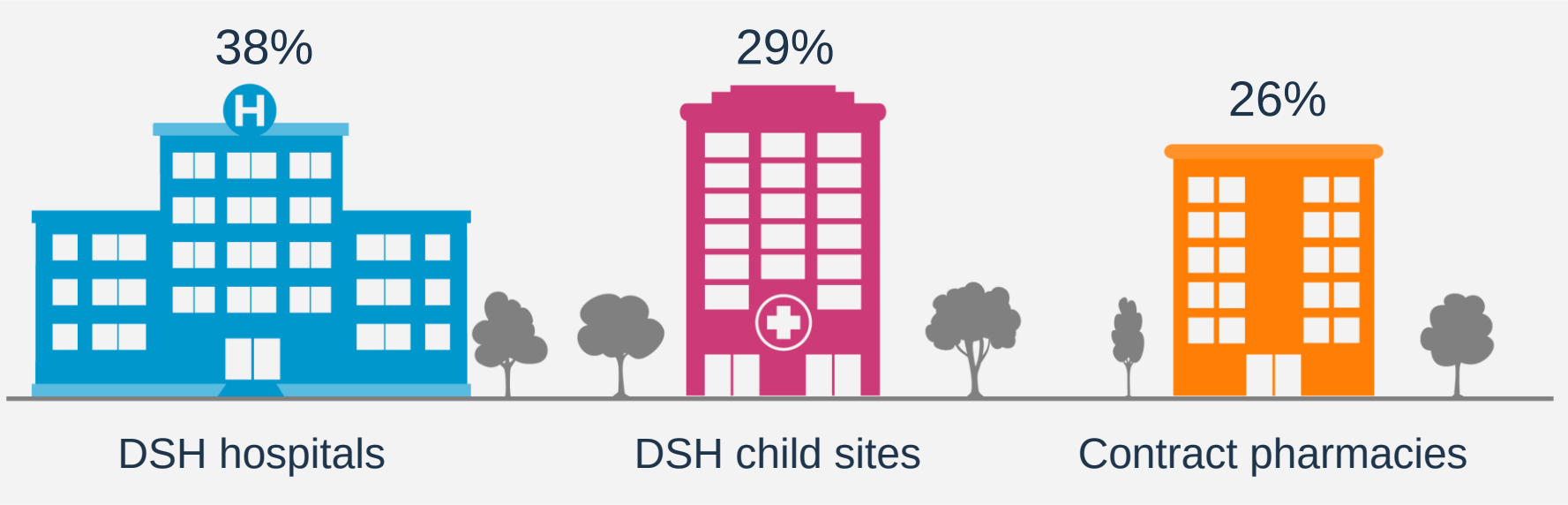
Sunita Desai, PhD, New York University; J. Michael McWilliams, MD, PhD, Harvard University[3]

1. Conti R, Bach P. Cost consequences of the 340B drug discount program. *JAMA.* 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156
2. Hunter MT, Gomberg J, Kim C; Milliman. Commercial payers spend more on hospital outpatient drugs at 340B participating hospitals. Published March 2018. Accessed April 2021. https://us.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2018/commercial-payers-spend-more-hospital-outpatient-drugs-340b-hospitals.ashx
3. Desai S, McWilliams JM. Consequences of the 340B drug pricing program. *N Engl J Med.* 2018; 378:539-548. doi:10.1056/NEJMsa1706475

Majority of 340B Entities Are Not in Vulnerable Communities the 340B Program Is Meant to Serve

Antithetical to the mission of the 340B program to help low-income and vulnerable populations, just a small share of 340B DSH hospitals, their child sites, and their contract pharmacies are located in medically underserved areas.

340B-Covered Entities in Medically Underserved Areas, 2021[1]



MEDICALLY UNDERSERVED AREAS:

Communities in the United States with too few primary care providers, high infant mortality, high rates of poverty, and/or a high elderly population, as defined by HRSA[2]

1. AmerisourceBergen, Xcenda. 340B and health equity: a missed opportunity in medically underserved areas. Published 2021. Accessed June 2022. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_issue_brief_340b_muas_nov2021.pdf
2. HRSA. MUA Find. Accessed June 2022. https://data.hrsa.gov/tools/shortage-area/mua-find

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**.

1. Government Accountability Office (GAO). Drug discount program: Federal oversight of compliance at 340B contract pharmacies needs improvement. Published June 2018. Accessed November 2021. https://www.gao.gov/assets/gao-18-480.pdf

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.

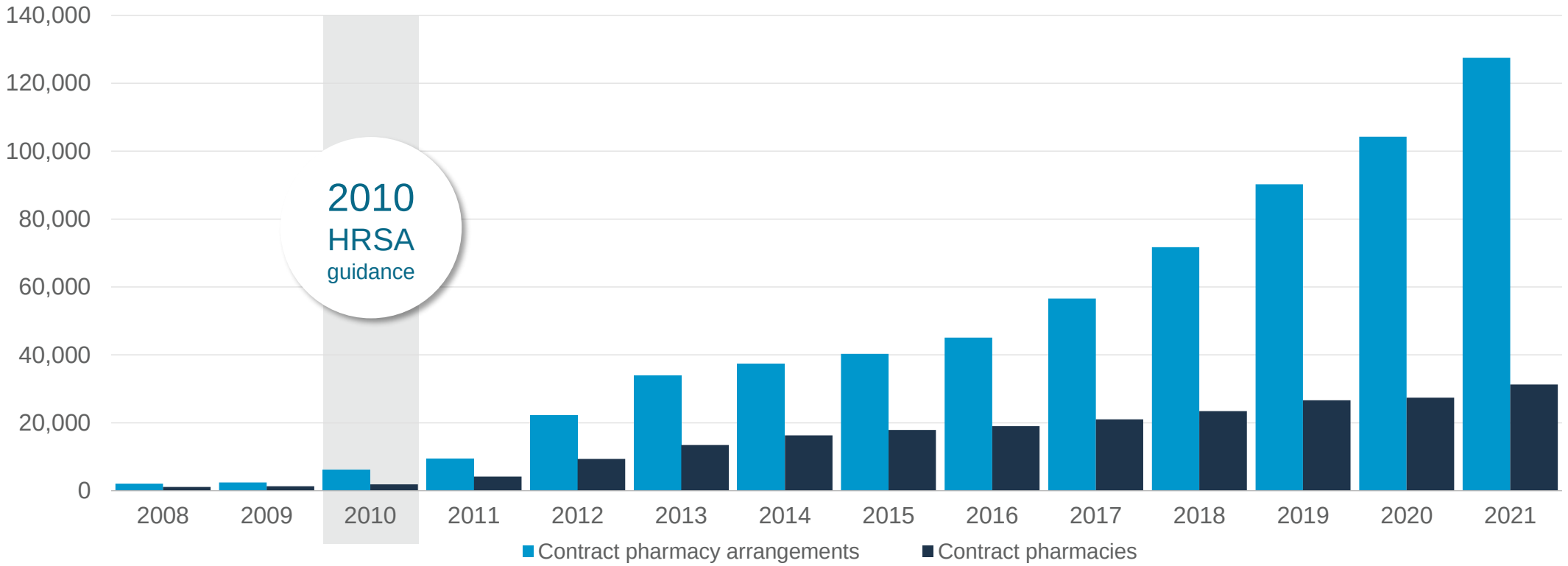
The hospital and pharmacy profit, while the patient may see no direct benefit from the 340B discount.

1. AIR 340B. The impact of growth in 340B contract pharmacy arrangements. Published Summer 2014. Accessed April 2015. https://340breform.org/wp-content/uploads/2021/04/FINAL.The-Impact-of-Growth-in-340B-Contract-Pharmacy-Arrangements.-AIR-340B.-July-14-2014.pdf

340B Contract Pharmacy Participation Has Increased Dramatically

The number of contract pharmacy arrangements has grown by more than 5,000% since the 2010 guidance. Currently, more than 30,000 distinct pharmacies participate in the 340B program, and each one may have arrangements with multiple entities.

340B Hospital Contract Pharmacies and Pharmacy Arrangements*



*A contract pharmacy may have multiple contracts with multiple 340B hospitals.

1. BRG analysis of HRSA OPA registrations. https://340bopais.hrsa.gov/ContractPharmacySearch

Contract Pharmacy Expansion Is Not Occurring in the Communities the Program Is Meant to Serve

Of the contract pharmacies in a different zip code than their parent DSH hospital, 60% were in areas with at least 10% higher median income, and more than 40% were in less diverse areas compared to their parent hospital.[1]

Growth in Share of 340B Contract Pharmacies in Specific Communities, 2011-2019[2]

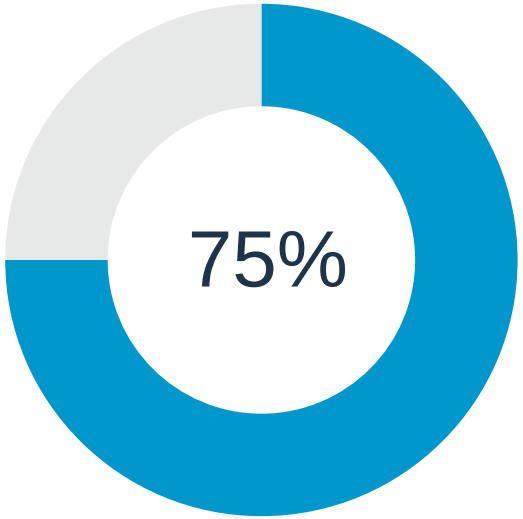
Growth of [pharmacy] contracts with 340B hospitals was less likely in areas with higher uninsured rates and in medically underserved areas."

Sayeh Nikpay, PhD, MPH, and Hannah Geressu, University of Minnesota; Gabriela Gracia, PhD, and Rena Conti, PhD, Boston University[3]

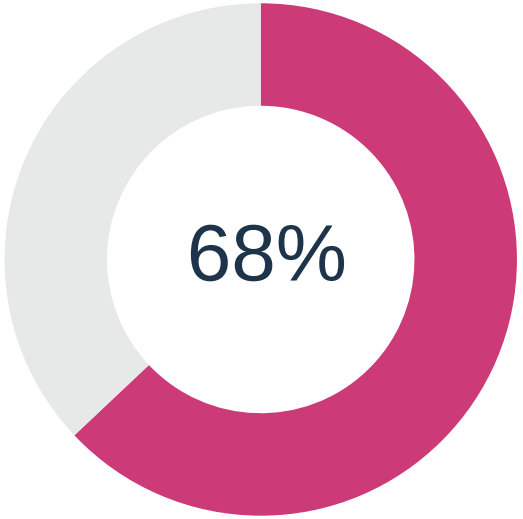
1. Isaiah E, et al; Avalere. 340B hospital child sites and contract pharmacy demographics. Published April 2022. Accessed July 2022. https://avalere.com/insights/340b-hospital-child-sites-and-contract-pharmacy-demographics
2. Lin JK, Li P, Doshi JA, Desai SM. Assessment of US pharmacies contracted with health care institutions under the 340B Drug Pricing Program by neighborhood socioeconomic characteristics. *JAMA Health Forum.* 2022;3(6):e221435. doi:10.1001/jamahealthforum.2022.1435
3. Nikpay S, et al. Association of 340B contract pharmacy growth with county-level characteristics. *Am J Manag Care.* 2022;28(3): 133-136. https://doi.org/10.37765/ajmc.2022.88840

For-Profit Pharmacies Have a Growing Financial Stake in the 340B Program

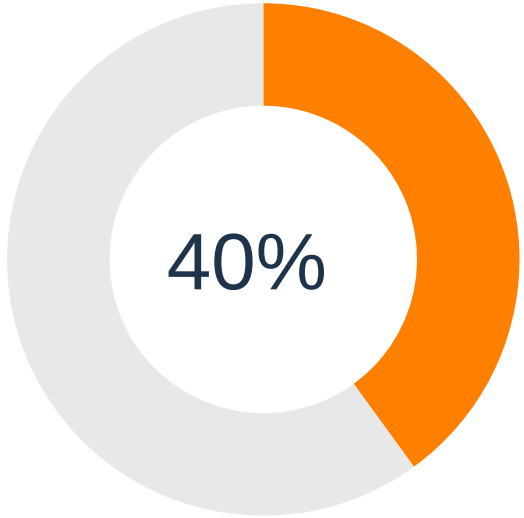
Although the 340B program was originally limited to safety-net providers, the current contract pharmacy guidance has given for-profit and vertically integrated pharmacies a big role in the program.



of contract pharmacies are chain pharmacies.[1]



of contract pharmacies are represented by CVS, Walgreens, Walmart, Rite-Aid, and Kroger.[1]



of contract pharmacy arrangements are between 340B entities and pharmacies associated with one of the three largest PBMs.[2,3]

PBM= pharmacy benefits management

1. GAO. Drug discount program. Federal oversight of compliance at 340B contract pharmacies needs improvement. Published June 2018. Accessed April 2021. https://www.gao.gov/assets/gao-18-480.pdf
2. Fein AJ; Drug Channels Institute analysis of OPA daily contract pharmacy database. Published April 2022. Accessed June 2022.
3. Fein AJ; Drug Channels Institute The 2022 economic report on US pharmacies and pharmacy benefit managers. Published March 2022. Accessed June 2022.

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.[1]

Vertical Integration of 340B Contract Pharmacies and Affiliates[2]*

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

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

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.

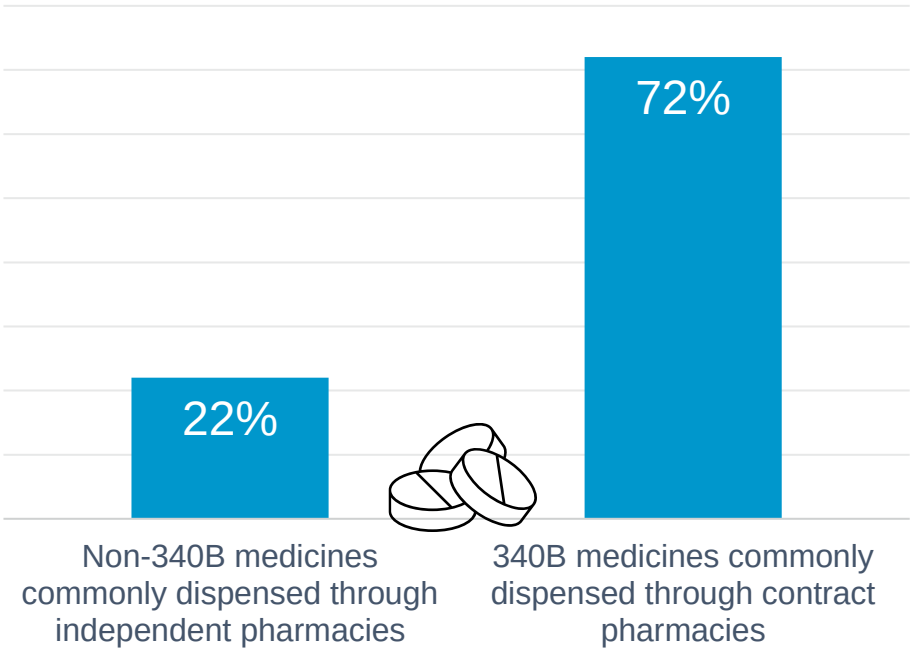
These corporations leverage their own contract pharmacies to maximize their potential 340B profits to drive program growth.

1. Fein AJ; Drug Channels Institute. Here's how PBMs and specialty pharmacies snag super-size profits from the 340B program. Published August 2019. Accessed April 2021. https://www.drugchannels.net/2019/08/heres-how-pbms-and-specialty-pharmacies.html
2. Vandervelde A, Erb K, Hurley L; BRG. For-profit pharmacy participation in the 340B program. October 2020. https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b

340B Program Profitable for Contract Pharmacies, Not Helping Patients

Despite exponential 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.[2]

Massive Profit Margin



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

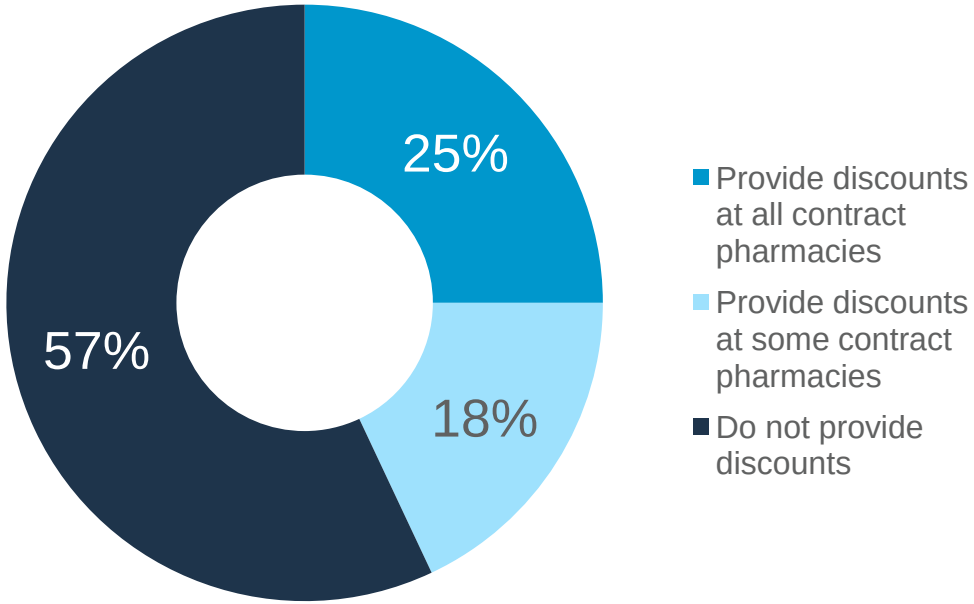
More than half of the top 20 companies on the Fortune 500 list generate revenue from 340B, whether as a contract pharmacy, third-party administrator, health plan, PBM, or wholesaler.[3]

1. Vandervelde A, Erb K, Hurley L; BRG. For-profit pharmacy participation in the 340B program. Published October 2020. Accessed April 2021. https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b
2. BRG analysis of HRSA OPA registrations. https://340bopais.hrsa.gov/ContractPharmacySearch
3. Fortune. https://fortune.com/fortune500/2022/search/

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.

Share of Hospitals That Reported Providing Discounts to Low-Income, Uninsured Patients on 340B Medicines Dispensed at Contract Pharmacies[1]



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[2]

1. GAO. Drug discount program: federal oversight of compliance at 340B contract pharmacies needs improvement. Published June 2018. Accessed June 2020. https://www.gao.gov/products/GAO-18-480
2. Office of Inspector General (OIG), HHS. Memorandum report: contract pharmacy arrangements in the 340B program. OEI-05-13-00431. Published February 2014. Accessed January 2021. https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

Government Watchdogs Note Concerns With Contract Pharmacies and Program Integrity

OIG (2014)[1]

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)[2]

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.

1. OIG, HHS. Memorandum report: contract pharmacy arrangements in the 340B program. OEI-05-13-00431. Published February 2014. Accessed April 2021. https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp
2. GAO. Discount drug program. Federal oversight of compliance at 340B contract pharmacies needs improvement. Published June 2018. Accessed April 2021. https://www.gao.gov/assets/gao-18-480.pdf

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.

Audit Findings Issued to Covered Entities by HRSA for Fiscal Years 2012-2019, as of September 2020

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

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."[1]

1. GAO. Drug pricing program: HHS uses multiple mechanisms to help ensure compliance with 340B requirements. GAO-21-107. Published December 2020. Accessed April 2021. https://www.gao.gov/assets/gao-21-107.pdf

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[1]

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

Office of Inspector General[2]

1. GAO. Drug pricing program: HHS uses multiple mechanisms to help ensure compliance with 340B requirements. Published December 2020. Accessed June 2021. https://www.gao.gov/assets/gao-21-107.pdf
2. OIG, HHS. Memorandum report: contract pharmacy arrangements in the 340B program. OEI-05-13-00431. Published February 2014. Accessed April 2021. https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

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[1]

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[2]

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[3]

1. GAO. Hearing Before the Subcommittee on Oversight and Investigations; Committee on Energy and Commerce, 115th Cong, 1st Sess (July 18, 2017). Comments from Debra Draper, Director, Health Care, GAO. p 33. Published July 2017. Accessed November 2021. https://www.govinfo.gov/content/pkg/CHRG-115hhrg26929/html/CHRG-115hhrg26929.htm
2. OIG. Hearing of the Committee on Health, Education, Labor, and Pensions United States Senate 115 Congress. Second session on examining oversight reports on the 340b drug pricing program. Comments from Ann Maxwell, Asst Inspector General for Evaluations and Inspections, OIG. p 9. May 15, 2018. Published May 2018. Accessed November 2021. https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/pdf/CHRG-115shrg30195.pdf
3. GAO. 340B drug discount program: increased oversight needed to ensure nongovernmental hospitals meet eligibility requirements. GAO-20-108. Published December 2019. Accessed November 2021. https://www.gao.gov/assets/gao-20-108.pdf

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

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