Profiting from 340B:

Understanding the Problems and Abuse of the 340B Drug Pricing Program

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The case for reforming 340B

- Out of control growth
- Not achieving its purpose
- Incentivizes the use of more expensive medicines
- Shifts drug costs to non 340B patients
- Incentivizes unwarranted consolidation of medical practices.

These inefficiencies are worsening the quality of the U.S. health care system

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340B's Purpose

- Ensure at-risk patients have access to needed medicines
- Fix snafu created by 1990 Medicaid Drug Rebate Program
  - Medicaid "best price" requirement eliminated company charitable programs to safety-net providers
  - 340B was implemented to improve the availability of medicines to safety-net facilities that serve vulnerable populations who lost access
  - Intention: reduce cost of outpatient drugs for true-safety net facilities serving large numbers of uninsured or vulnerable patients
  - Discounts can be upwards of 50% or more

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The 340B Discount: A Simplified Example

Drug price	-$1,000
340B Discount	-50%
Cost to 340B Institution	-$ 500
Reimbursement from Insurer	+$1,000
Net Income to 340B Institution	+$ 500

Eligibility based on institution not patient

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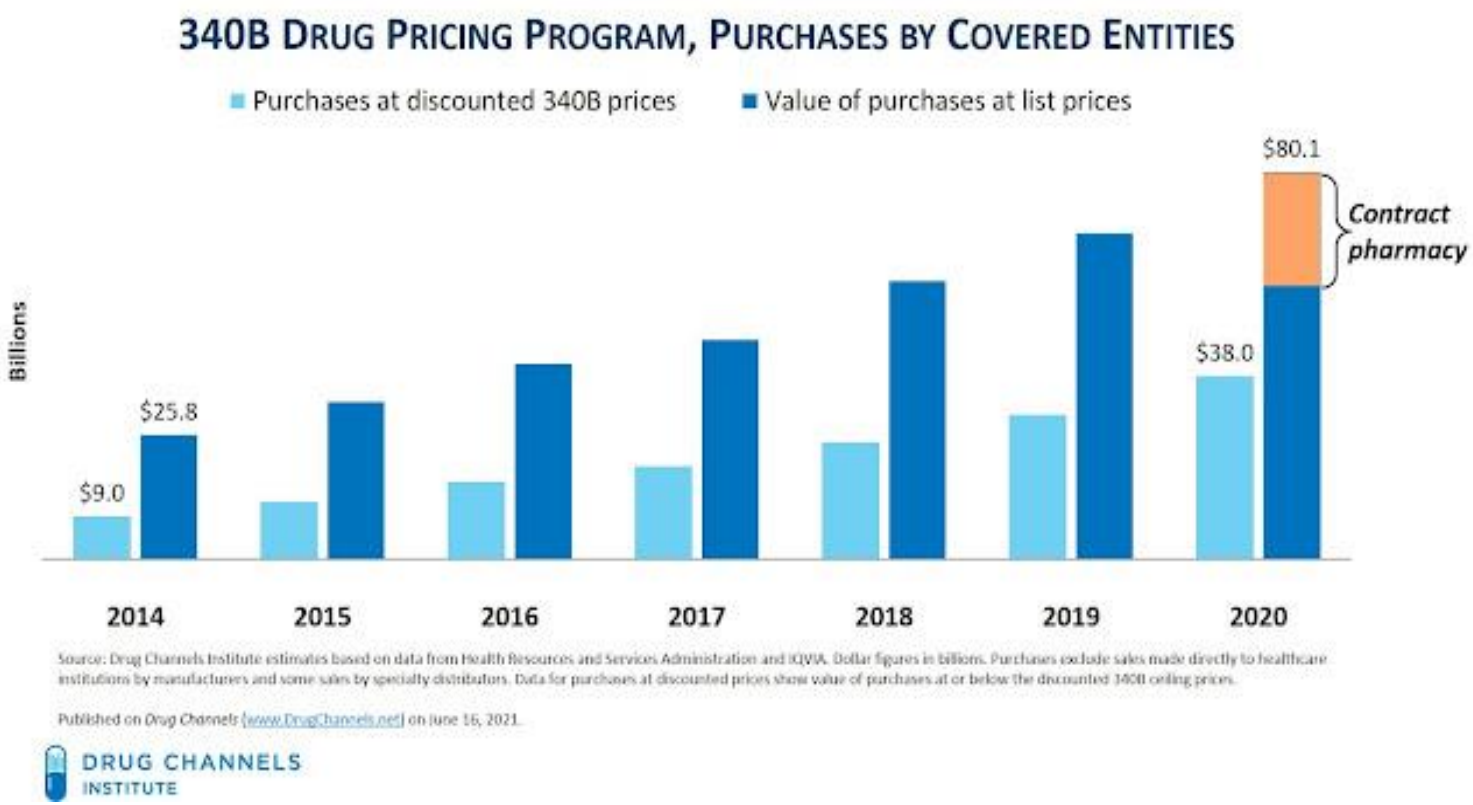
Out of Control Growth

- 340B discounted purchases grew 27.1% between 2014 and 2020 compared to 5% growth in manufacturers' net revenues*



* Growth measured as the compound average growth rate (CAGR)

https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html

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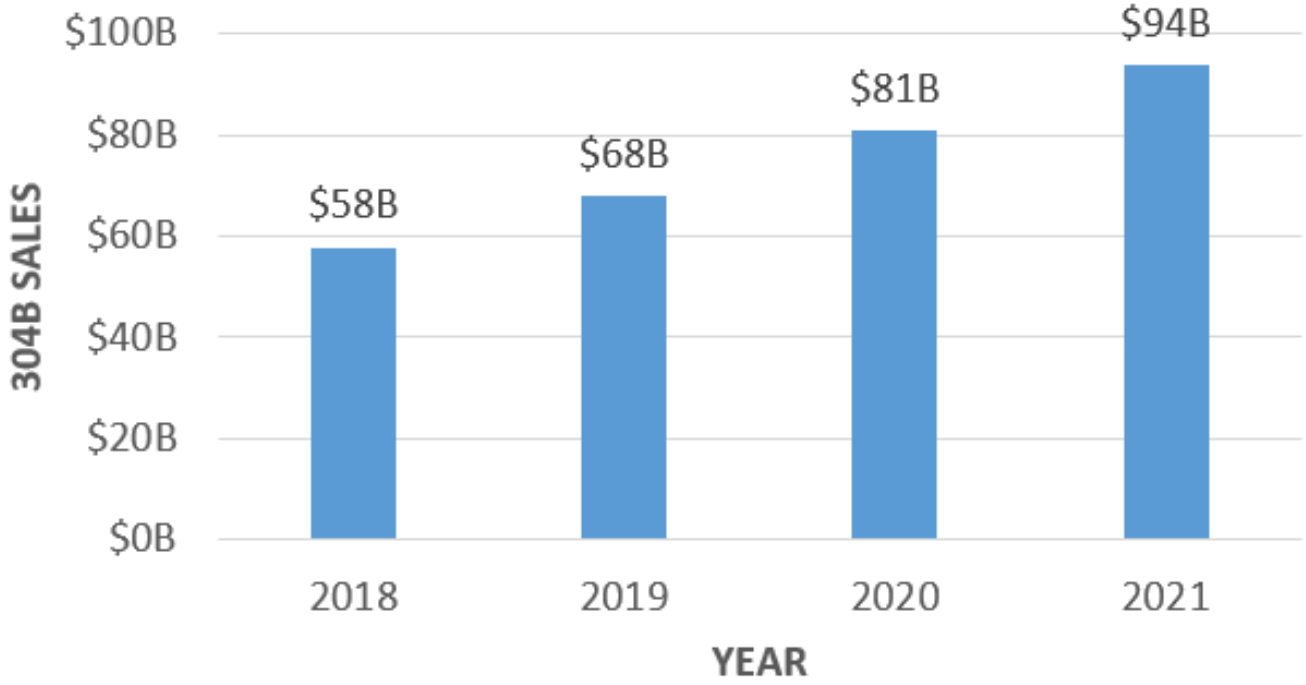
Out of Control Growth

- In 2021, 340B program sales reached $93.6 billion or 14% of total pharmaceutical sales of $668.3 billion



Source: IQVIA

https://www.iqvia.com/locations/united-states/blogs/2022/04/340b-program-continues-to-grow-while-contract-pharmacy-restrictions-take-effect#:~:text=In%202021%2C%20340B%20program%20sales,%25%20growth%20in%202020%2C%20respectively.

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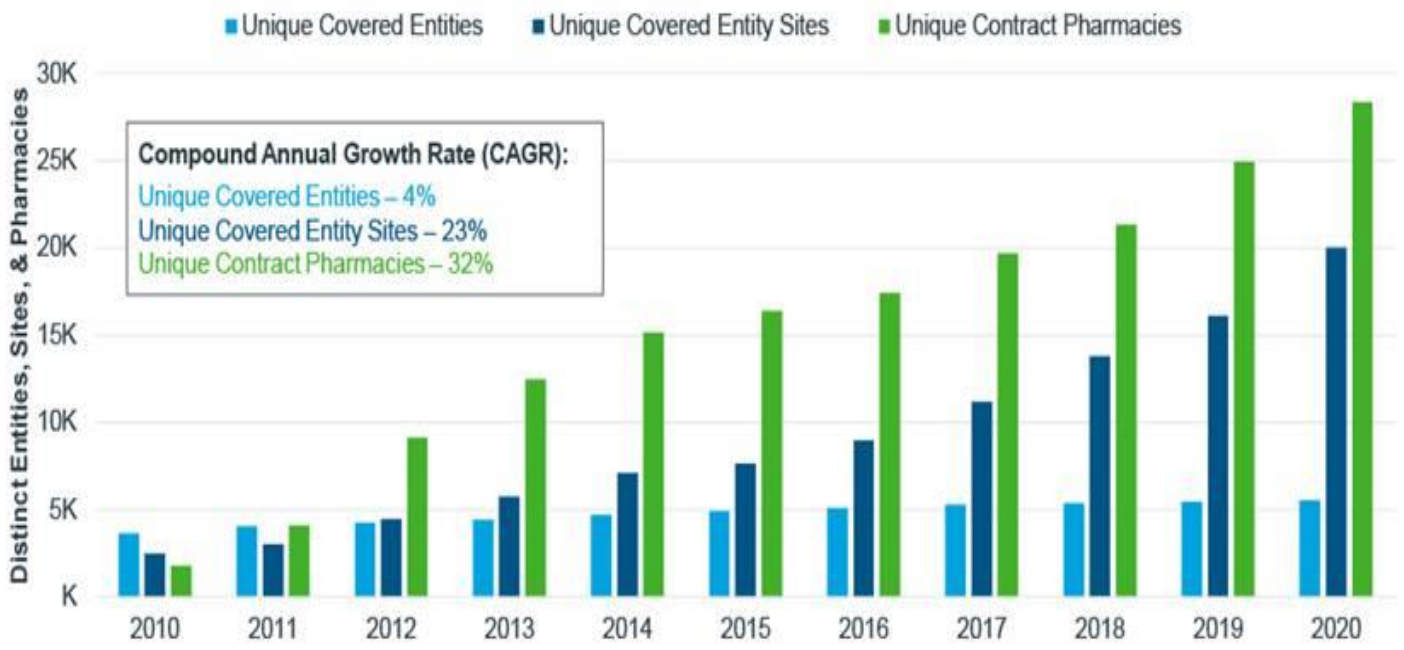
Out of Control Growth

- Between 2010 and 2020:
  - Covered entities grew 50% (3,600 to more than 5,000)
  - The number of contract pharmacy sites grew seven-fold
  - Expansion of Medicaid and relaxation of limits on contract pharmacies fueled expansion



https://www.iqvia.com/locations/united-states/blogs/2021/04/340b-drug-discount-program-growth-drivers

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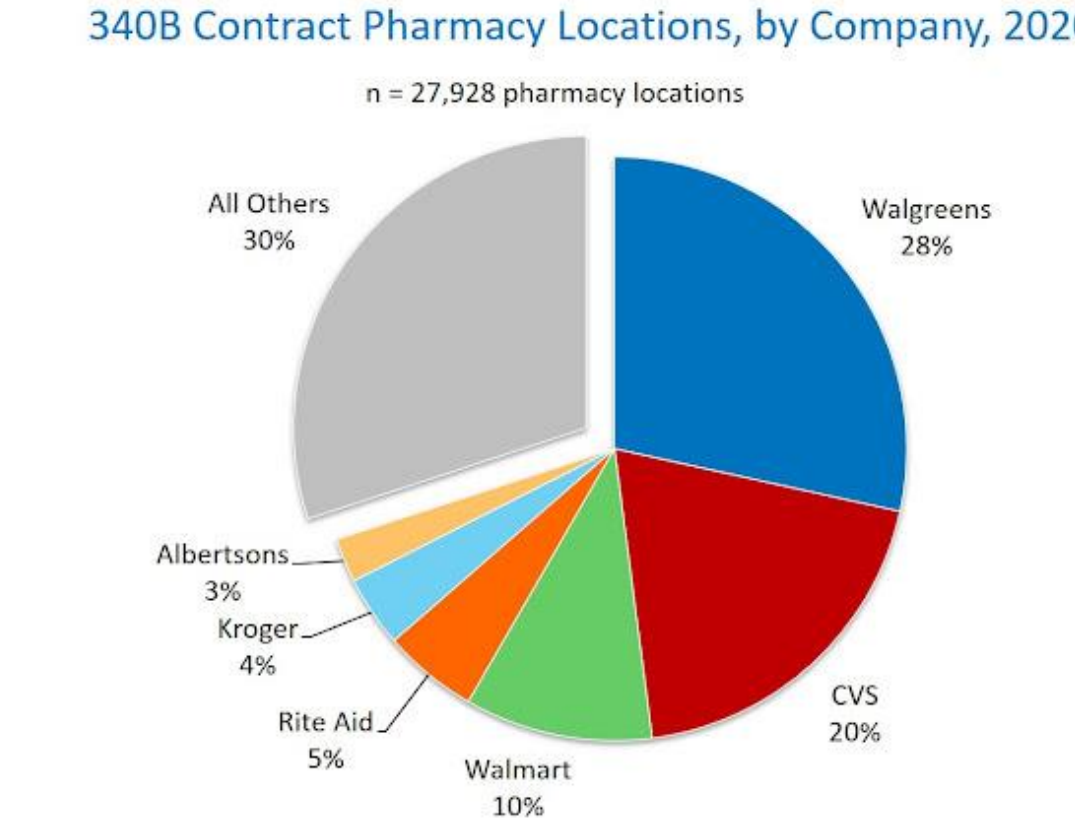
Not Achieving Its Purpose

- Unique contract pharmacy locations grew from 1,300 as of January 2010 to 27,928 unique locations as of July 2020



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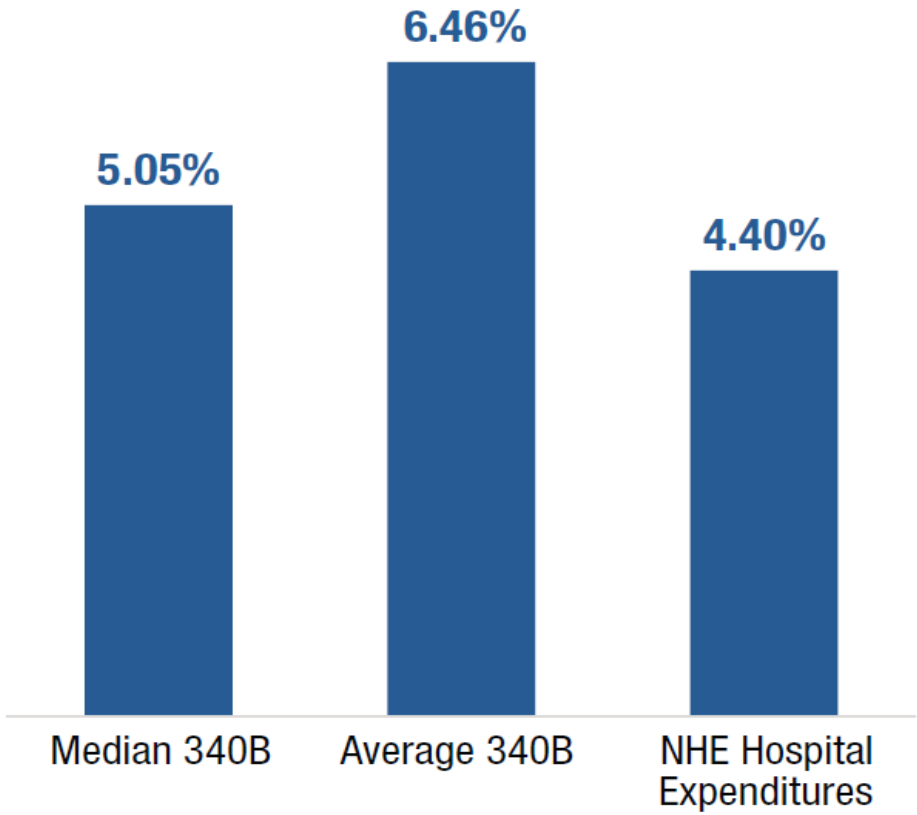
Not Achieving Its Purpose

Average Annual Revenue Growth

All Hospitals versus Sample of 340B Hospitals, 2010 – 2019



Source: Winegarden W "Profiting from 340B, PRI , November 2021
Author calculations based on CMS Medicare Hospital Cost Report Data and individual hospital 990 filings
Sample of 25 large hospitals

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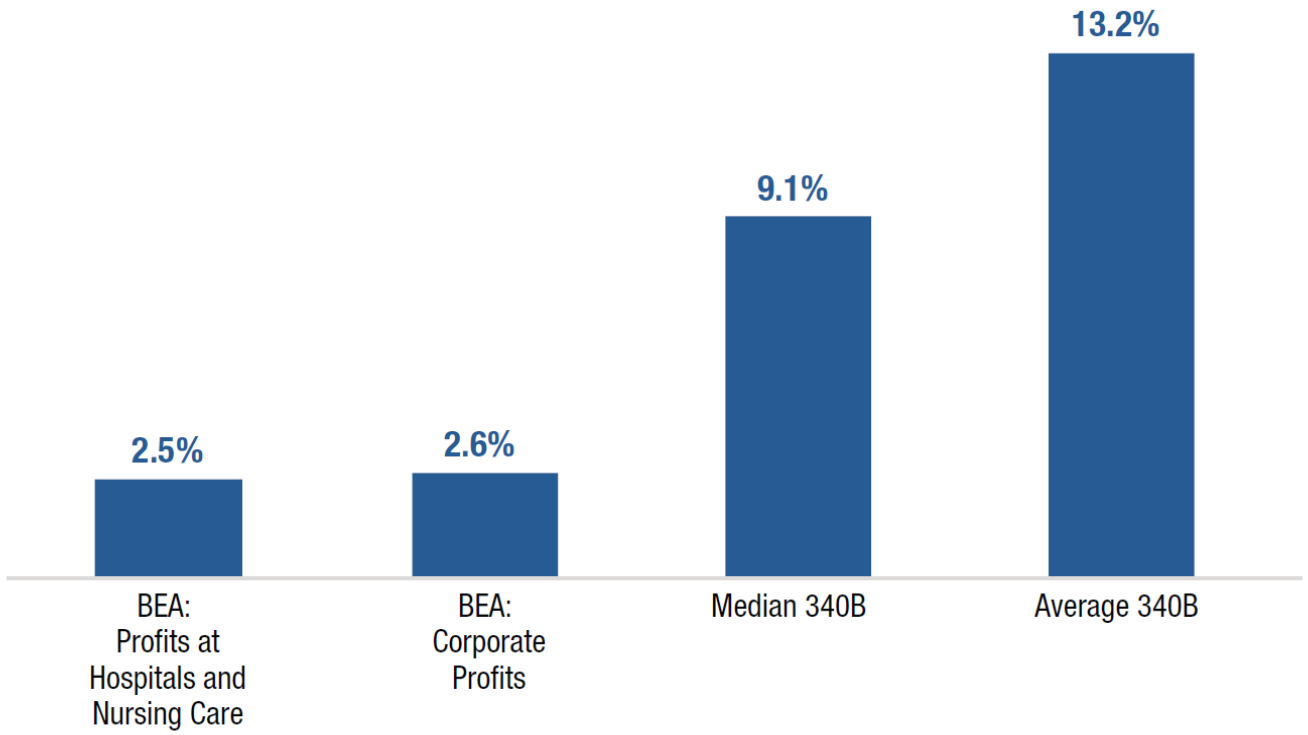
Average Annual Profit Growth

All Hospitals versus Sample of 340B Hospitals, 2010 – 2019



Source: Winegarden W "Profiting from 340B, PRI , November 2021
Author calculations based on CMS Medicare Hospital Cost Report Data and individual hospital 990 filings
Sample of 25 large hospitals

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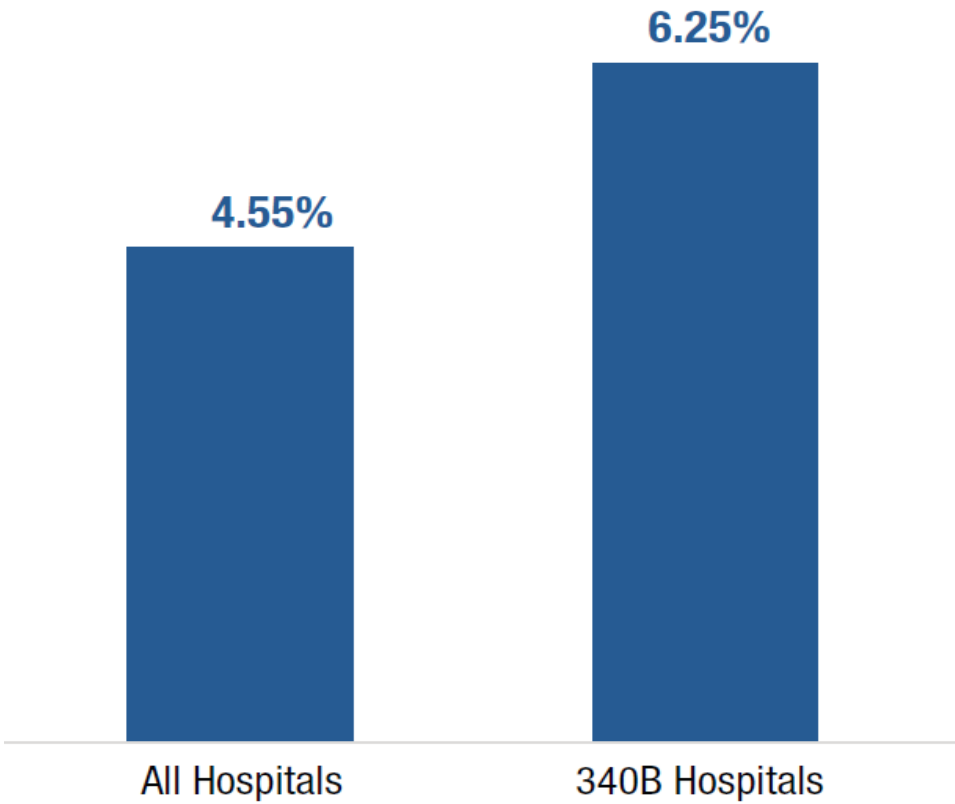
Not Achieving Its Purpose

Net Income as a Percentage of Net Patient Revenues
All Hospitals versus 340B Hospitals, 2017



Source: Winegarden W "Profiting from 340B, PRI , November 2021
Author calculations based on CMS Medicare Hospital Cost Report Data
Health Resources & Services Administration, Office of Pharmacy Affairs 340B OPAIS

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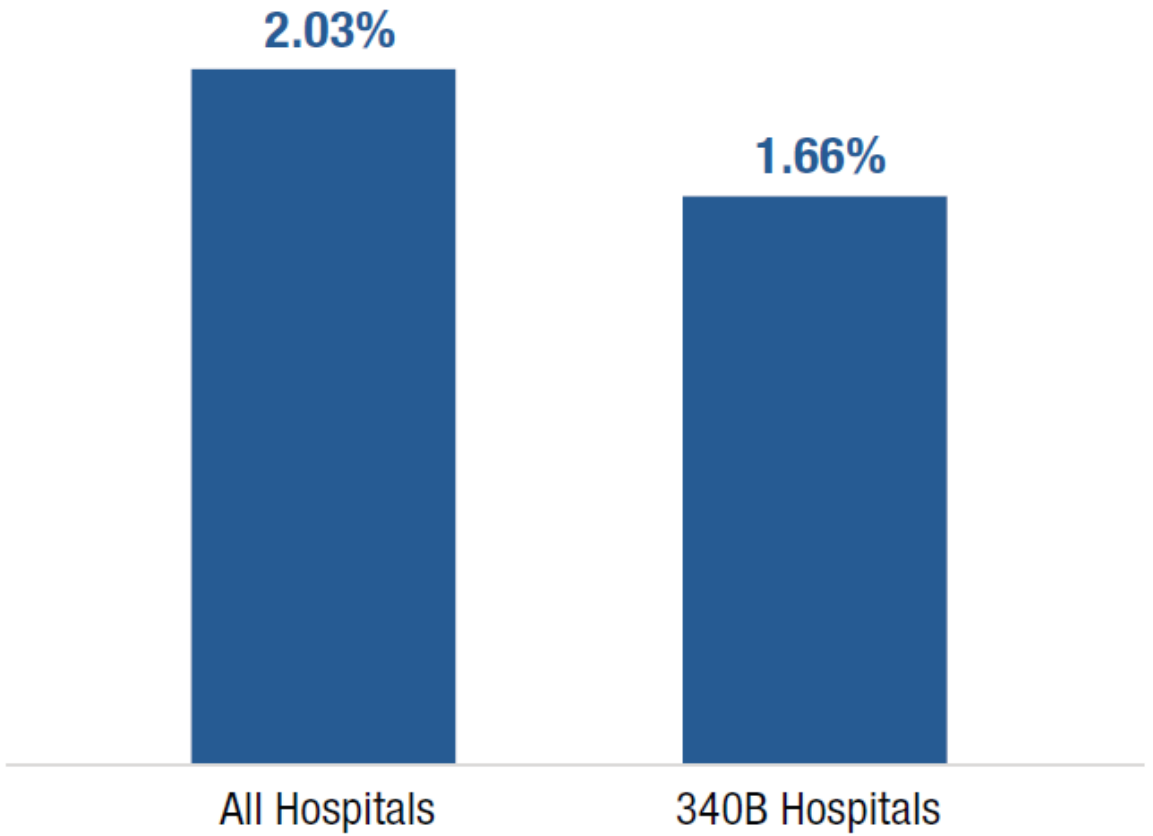
Charity Care as a Percentage of Net Patient Revenues
All Hospitals versus 340B Hospitals, 2017



Source: Winegarden W "Profiting from 340B, PRI , November 2021
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Incentivizes High-Cost Medicines

- 340B Profit Loophole:
  - Once hospital designated 340B, can sell the medicine to all patients regardless of their income and insurance status
  - 340B discounts are a percentage of a drug's cost
  - Hospitals earn more revenue when prescribe most expensive drug possible

More expensive medicines generate larger dollar spread between discounted 340B price and the reimbursed amount

Incentivizes High-Cost Medicines

According to the GAO

"there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries. …

on average, ***beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs*** *than beneficiaries at the other hospitals in GAO's analysis."*

For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. ***The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status."***

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Inequitable Drug Cost Shifting

The GAO (2011),

"as the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the ***potential for unintended consequences, such as cost-shifting to other parts of the health care system."***

"Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" Government Accountability Office, September, GAO-11-836.

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Inequitable Drug Cost Shifting

"the scope of the 340B program is currently so vast ***...that their prices are probably driven up for all consumers.*** *... Better targeting of the 340B program might improve affordability for patients in need while lowering prices for other payers."*

http://www.nejm.org/doi/full/10.1056/NEJMp1515068?rss=searchAndBrowse&#t=article

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Unwarranted Consolidation of Medical Practices

- Under 340B program rules:
  - Independent physician offices not eligible for discounts
  - Hospital outpatient departments and their *offsite outpatient facilities* are eligible.

"The 340B Program has been associated with hospital–physician consolidation in hematology–oncology and with more hospital-based administration of parenteral drugs in hematology–oncology and ophthalmology."

Source: Consequences of the 340B Drug Pricing Program, New England Journal of Medicine

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Complexity Causes Unintended Consequences

- Reforms to rein in the program include:
  - Require 340B healthcare providers and hospital systems serve the intended low-income populations
  - Ensure that patients directly benefit from the financial discounts when receiving their medications
  - Restrict the scale and scope of the contract pharmacy program
  - Restrict expansion to medically underserved areas
  - Require transparency – hospitals should have to disclose their 340B revenues