State of Connecticut
Department of Social Services

APPENDIX

to

Report Regarding the Drug Discount Program Established Pursuant to Section 340B of the Federal Public Health Service Act, Pursuant to Section 16 of Connecticut Public Act 23-171

January 31, 2024 (Updated Version)

STATE OF CONNECTICUT

DEPARTMENT OF SOCIAL SERVICES

55 FARMINGTON AVENUE • HARTFORD, CONNECTICUT 06105

Working Group for the Prescription Drug Pricing Program Pursuant to Section 340B of the federal Public Health Service Act (Established by Connecticut Public Act 23-171, Section 16)

MEETING MINUTES for November 7, 2023 Meeting

1. Introductions. Workgroup members introduced themselves.

2. Overview of Workgroup's Purpose: Mehul Dalal, DSS, read the statute that is the basis for this working group:

> CT Public Act 23-171, Sec. 16. (Effective from passage) "(a) The Commissioner of Social Services shall convene a working group to evaluate (1) the current status of the federal 340B drug pricing program authorized by 42 USC 256b, as amended from time to time, (2) national efforts to strengthen and sustain such program, and (3) opportunities for state action to protect 340B revenues of federally qualified health centers from unfair administrative barriers or unnecessary conditions based on such centers' status as a 340B covered entity. Such evaluation shall consider (A) the ability of and any legal precedent for states to regulate the conduct of drug manufacturers and pharmacy benefits managers, as defined in section 38a-479aaa of the general statutes, (B) opportunities to facilitate patient access to on-site pharmacies of a federally qualified health center, (C) opportunities to establish on-site pharmacies across federally qualified health centers, and (D) national trends to sustain such program. As used in this subsection, "340B covered entity" means a provider participating in the federal 340B drug pricing program authorized by 42 USC 256b, as amended from time to time.
>
> (b) Not later than January 31, 2024, the Commissioner of Social Services shall report, in accordance with the provisions of section 11-4a of the general statutes, on the findings and recommendations of the working group to the joint standing committees of the General Assembly having cognizance of matters relating to insurance, public health and human services."

3. National Landscape and Trends of 340B Program

Drew Gattine, NASHP: Walked through slide presentation on key elements of 340B program, including that it has significantly increased as a proportion of drug purchasing. Congressional intent to make federal funds go as far as possible. It is a federally administered program by the Health Resources Services Administration (HRSA) Office of Pharmacy Affairs, which is a key reason that historically, states did not take much action on 340B. Initial federal law provisions of 340B had a narrow set of covered entities and narrow rules on the potential use of contract pharmacies.

The program was changed by federal law over time to expand the scope of covered entities to include more hospitals and sites affiliated with hospitals and the expansion of unlimited number of contract pharmacies. Significant proportion is participation by disproportionate share hospitals (DSH). As a

result, significant expansion in the number of covered entities and contract pharmacies. Significant financial growth in the scope of program

Complex rules for flow of funds with contract pharmacies under 340B program.

Sample of state activity to date, including some states regulating pharmacy benefit managers (PBMs) and other attempts by payers to provide lower reimbursement to covered entities for 340B purchased drugs. Some states have passed laws (Louisiana, Arkansas) to address situations of contract pharmacies. Recent bills have been proposed in the state legislatures of Iowa, Louisiana, and Nevada.

Transparency legislation passed in 2023 in Maine (beginning in 2024 requires hospitals to report on 340B expenditures, savings, and use of the savings), Minnesota (reporting requirements for covered entities to report drug acquisition costs), and Washington State (requires the state to establish a reporting requirement for 340B covered entities).

Q. Gui Woolston, DSS: What are states' levers to be able to take action regarding 340B?

A. Drew Gattine: There are limited options but states are trying to gather more information to be able to consider other drug pricing regulation because they do not yet have the data. States perceive the program as originally intended to improve access for individuals with low-income. States also trying to understand implications for carve-in or carve-out (such as Oregon and California).

Q. CT State Sen. Somers: Recommends representation from PhRMA and PNPs on this workgroup. What opportunities does a state have on regulating 340B, including status of lawsuits in other states? Also referencing transparency. Aware that hospitals have used these funds for capitalization funds.

A. Drew Gattine: In Arkansas, state defended its statute in federal district court, currently on appeal to federal circuit court of appeals. In Louisiana, the drug manufacturers have sued the state to challenge the statute.

A. Mehul Dalal, DSS: DSS welcomes the opportunity to invite industry representatives and had previously reached out to a lobbyist for PhRMA but had not received a response.

Sen. Somers: There needs to be more education of legislators and the public on how 340B actually works, which is much more complex than most assume.

4. Summary of the Current Status of the 340B Program in Connecticut

Herman Kranc, DSS: DSS uses a 340B exclusion file to ensure that CT Medicaid does not pay based on a duplicate discount because federal law prohibits both 340B discount and Medicaid prescription drug rebate.

Nina Holmes, DSS: DSS ensures that those rules are followed across providers other than those enrolled as pharmacies.

Mehul Dalal, DSS: DSS will provide a brief written overview.

Sabrina Griswold, First Choice Community Health Center (designated representative of the Community Health Center Association of CT) explained that FQHC expanded to additional contract pharmacies; eventually the in-house pharmacy also opened; that FQHC's 340B savings are used to expand services for any area that the FQHC determines are needed (including: LGBTQ program, medication-assisted treatment program, optometry services and retail vision services, opening additional sites). She also sits on the DSS pharmaceutical and therapeutics committee. As a Medicaid fee-for-service only state, in order to prevent duplicate discounts, the provider needs to have a different NPI to ensure that the 340B discounts are captured but very few pharmacies have different NPIs. Believes that there are no duplicate discounts happening. Different impact on FFS vs. MCO Medicaid states.

Paul Kidwell, CT Hospital Association: All but one hospital in CT participates in 340B program through the DSH eligibility (about 15, different thresholds set in federal statute). For-profit hospitals are not eligible to participate in 340B. Hospitals use the savings to stretch scarce resources. Nonprofit hospitals report to the IRS on Medicaid underpayment, uncompensated care, and community benefits. Medicare reimbursement for hospitals starting in 2018 reduced payment for 340B drugs, U.S. Supreme Court affirmed decision in favor of hospitals, and just last week, CMS revised the Medicare reimbursement methodology.

5. Proposed Agendas for Upcoming Meetings

Need to ensure that the workgroup addresses the remaining pieces of the statutory requirements and incorporates feedback from this working group.

The upcoming meetings of the workgroup will be Tues. 11/28 at 9am and Tues. 12/19 at 9am

6. Process for Gathering Feedback from Workgroup Members

There was a brief conversation about the process for working group members to share information and feedback with DSS that can then be shared with the entire working group, including at future meetings.

7. Other Business

There was no other business identified.

8. Adjourn

The working group adjourned.

STATE OF CONNECTICUT

DEPARTMENT OF SOCIAL SERVICES

55 FARMINGTON AVENUE • HARTFORD, CONNECTICUT 06105

Working Group for the Prescription Drug Pricing Program Pursuant to Section 340B of the federal Public Health Service Act (Established by Connecticut Public Act 23-171, Section 16)

MEETING MINUTES for November 28, 2023 Meeting

1. Introductions

Mehul Dalal, DSS, summarized the agenda for the meeting and introduced Bill Smith, Pioneer Institute. Lara Manzione, OSC, introduced herself. Other individuals previously introduced themselves during the November 7, 2023 meeting.

2. Brief Summary of November 7, 2023 Meeting

Mehul Dalal, DSS, briefly summarized the previous meeting.

3. Discuss Each Specific Provision of PA 23-171, Sec. 16

There was a brief description of the provisions of PA 23-171, Sec. 16.

Bill Smith, Pioneer Institute, gave a presentation on, among other topics, national trends of the 340B program using PowerPoint presentation, which includes a summary of the history of the program based on federal law and incentives for hospitals to buy drugs at a discount and bill at the standard Medicare or commercial insurance rates, as applicable, more straightforward scenario for uninsured individuals. There has been significant growth in the program, which was intended to support hospitals serving low-income and uninsured individuals. At the same time that 340B has grown, overall average charity care percentage has declined, primarily for hospitals, less significant for clinics, which generally provide more charity care. Summarized the Pioneer Institute web tool to analyze 340B program growth, legislative district mapping, and hospital charity care. There has been significant increases in growth, especially since 2011 when the U.S. Department of Health and Human Services (HHS) removed the cap on 340B contract pharmacies. The tool also shows the prevalence of 340B covered entities in lower vs. upper income areas, some states have comparable or higher concentrations in upper income areas. He summarized suggestions for what states can do to reform the 340B program. Identified uncontrolled 340B growth with declining charity care—states can require 340B covered entities to disclose 340B revenue and charity care spending (under a uniform definition). Focus on improving transparency. Recommends identifying underserved and overserved offices, including satellite offices in upper income areas to leverage more generous insurance, suggests using the Pioneer Institute website tool and hold hearings to improve transparency. Website is: https://pioneerinstitute.org/340babuse

Q. CT State Sen. Heather Somers: Original federal 340B bill has confused many people. How does the billing occur?

A. Bill Smith: 340B statute does not require how the 340B covered entity must bill the payers related to the 340B discount, federal 340B statute allows the covered entity to bill in the same manner and what the patient pays is not in statute. The 340B statute does not specify who can be a patient served by the program.

Q. CT State Sen. Somers: Example of a product that is purchased at a tiny amount but billed to the patient or the insurance at a much, much higher amount. Only recent legislation requiring the covered entity to report on the details. Is it wholesale or list price?

A. Bill Smith: The commercial insurer or Medicare would pay a percentage of the list price, not the full amount.

Q. Gui Woolston, DSS: How is the tool used to compare concentration of 340B entities relate to changing the policy in practice?

A. Bill Smith: Limited state ability to change the policy outcome because 340B is federal law, but the tool can be used to improve transparency.

Q. Paul Kidwell, CT Hospital Association (CHA): Where does the Pioneer Institute receive its funding?

A. Bill Smith: Pioneer gets a mixture of types of funding, including pharmaceutical industry; he is a former Pfizer executive.

Sabrina Griswold, Designee of Community Health Center Association of CT (CHCACT): The misuse of 340B has been shown to be primarily by hospitals, not FQHCs, which help serve uninsured and underinsured patients. Recommends looking at impact on hospitals vs. non-hospitals. States that FQHCs are directly passing on the savings to patients but challenges if the FQHC does not have an in-house site and problematic because the contract pharmacy does not have the ability to pass along the discounts to uninsured patients.

Q. Joel Norwood, DSS: Any examples of states taking action to address issues identified in Bill Smith's presentation?

A. Bill Smith: Not aware of states taking action but recommends federal statutory changes and more transparency.

Sen Somers: Although FQHCs also provide care to low-income individuals, also recommends that FQHCs (and any other 340B covered entities) must also have transparency. Also recognizes the challenges if an FQHC does not have an in-house pharmacy in certain contexts.

Drew Gattine, NASHP: A lot of the data that NASHP has collected aligns with the data that Mr. Smith presented. There were three states that passed some type of transparency, Minnesota, Maine, and Washington State. Can provide the actual language for those bills, each of them different but all in common in improving transparency.

Zoom Chat Note: Paul Kidwell 9:36 AM

Each year CHA issues a report on hospital community benefits. The last reported year's report (2021) can be found here:
https://www.cthosp.org/documents/web/CHA%20website/2023%20toolkit/FINALCBRprint.pdf

Nonprofit hospitals report community benefit to the IRS annually; and CHA compiles that information to prepare a report on hospital community benefits.

4. Process for Gathering Feedback from Workgroup Members

There was a brief discussion about DSS requesting working group members to send documentation related to the provisions of Public Act 23-171, section 16.

CHA plans to put together a more formal presentation

Sabrina Griswold will reach out to CHCACT to gather additional information specific to the provisions of the statute. Felipe also agreed to gather information on behalf of Community Health Center (CHC), Inc. (based on information in the meeting chat, since he indicated that his internet connection on the Zoom meeting was unstable.

5. Proposed Agenda for Upcoming Meeting

Patricia McCooey, Assistant Attorney General, CT Attorney General's Office (AGO): Next meeting, AGO will summarize their activity related to 340B program and pharmacy pricing more generally and request information. States are key stakeholders in the 340B program and monitoring litigation regarding federal preemption and ERISA preemption.

Paul Kidwell, CHA agrees with having helpful context of litigation across the country on 340B.

6. Other Business

No other business was identified.

7. Adjourn

The meeting was adjourned.

STATE OF CONNECTICUT

DEPARTMENT OF SOCIAL SERVICES

55 FARMINGTON AVENUE • HARTFORD, CONNECTICUT 06105

Working Group for the Prescription Drug Pricing Program Pursuant to Section 340B of the federal Public Health Service Act (Established by Connecticut Public Act 23-171, Section 16)

MEETING MINUTES for December 19, 2023 Meeting

1. Introductions

Mehul Dalal, DSS, summarized the agenda for the meeting.

2. Brief Summary of November 28, 2023 Meeting

Mehul Dalal, DSS, briefly summarized the previous meeting.

3. Presentation from Attorney General's Office (AGO) (see presentation document for more details and context)

Patricia McCooey, AAG, AGO Health and Education Unit, presented an overview of the CT AGO's (also known as OAG) actions regarding 340B. OAG has been working to facilitate 340B covered entities to be able to obtain 340B drugs and the position that drug manufacturers should not be able to unilaterally impose their own conditions on acquisition of 340B drugs. The program has grown substantially due to federal allowance of 340B contract pharmacies for covered entities.

Summary of timeline of the OAG's involvement during 2020-2023, including letters to pharmaceutical manufacturers and engagement with HHS and amicus briefs in two federal court cases arguing that the manufacturers are not authorized to impose unilateral changes to program participation requirements. Multistate letter from various state attorneys general arguing that Congress should authorize more regulatory authority to HHS HRSA in order to ensure integrity and sustainability of the 340B program.

Rahul Darwar, AAG, AGO Antitrust and Government Fraud Unit, summarized various aspects of recent litigation regarding 340B, including:

Contract pharmacy litigation: HRSA issued violation notices to pharmaceutical manufacturers and they challenged in federal court arguing that 340B does not require delivery of drugs to an unlimited number of contract pharmacies. 3rd circuit held that it was not required; the other two circuits considering that question have not yet ruled.

Federal preemption litigation: Pharmaceutical manufacturers argued that various state statutes seeking are preempted by 340B, trial court held that the Arkansas statute was not preempted, currently on appeal to the 8th circuit. Similar case in Louisiana.

Patient definition litigation: definition of eligible patients, federal trial court in S. Carolina.

State Transparency Requirements: Minnesota and Maine recently passed state transparency laws, neither has yet been challenged in court.

Q. Bill Smith, Pioneer: Has CT OAG looked at duplicate discounts where a covered entity contract pharmacy has claimed both Medicaid rebate and 340B discount.

A. Rahul Darwar, AAG: Not aware of CT OAG looking into that issue.

A. Patricia McCooey, AAG: Confirmed that CT OAG has not investigated; aware that CT DSS takes steps to ensure that there are not duplicate discounts to comply with federal prohibition on duplicate discounts. Simpler to administer in CT because there are no Medicaid managed care organizations.

A. Herman Kranc, DSS: Both HRSA and manufacturers have a right to rebate. CT DSS uses a Medicaid exclusion file from HRSA to ensure compliance with the prohibition on duplicate discounts to ensure that DSS is not invoicing for rebate when the pharmacy is on the HRSA exclusion file.

Q. Drew Gattine, NASHP: In addition to Maine and Minnesota, Washington State also recently passed a statute requiring its state health authority to develop regulations to require transparency. Will send a link to the new state statutes and side-by-side comparison.

4. Presentation from Pharmaceutical Manufacturer

Daniel Vigil, Director of State Policy, Novartis: Concerns with some of the growth of 340B and reasons why states should not place restrictions on requiring pharmaceutical manufacturers to provide unlimited 340B discounts to contract pharmacy. 2nd largest drug program and significant increase. Believes there is essential federal reform.

Data points: of the 1041 contracts between 16 hospitals, only 19% of the contract pharmacies are in CT; important that there is no restriction on the hospitals charging the discount price to patients, which enables hospitals to have a large profit from that margin; more than half of the profits are retained Walgreens, Walmart, CVS, Creedo (Express Scripts and Cigna), which are for-profit entities, more than $10 billion in profits. Pharmacy benefit managers often involved in these arrangements and get over $2 billion in profits and often own the third party administrators.

Believes that states should pause and not adopt mandates on pharmaceutical manufacturers related to contract pharmacies. There is no federal statute regarding contract pharmacies, only federal HRSA guidance. Federal government has a pervasive and nationwide federal regulatory structure under 340B, if states adopt individual requirements, can be unmanageable for manufacturers. Some of the state statutes' mandates are being challenged as unconstitutional; and requiring additional contract pharmacies will even further distort the 340B program by not actually benefiting the intended beneficiaries; GAO report on 340B covered entities that more

than half of the hospital covered entities did not share their discounts with patients for contract pharmacies; JAMA (?) article showing that the contract pharmacy arrangements are concentrated in affluent communities with significant rates of commercial insurance.

Q. Paul Kidwell, CT Hospital Association: What is the definition of "medically underserved" referenced by Mr. Vigil.

A. Daniel Vigil: PhRMA report cross-referenced other report; will provide the reference.

Q. Sabrina Griswold: Novartis is a for-profit company, so by restricting access to contract pharmacy 340B discounts, that discount would go to Novartis rather than being discounts available to low-income individuals.

A. Daniel Vigil: Novartis supports a variety of patient assistance programs, including participation in 340B, Medicaid and other.

Q. Sabrina Griswold: How do low-income patients become aware of the drug discount programs? Pharmacy itself may not necessarily be in an underserved area but patients may be accessing from other locations; more nuanced in terms of how to show actual low-income individuals' access to drug discounts, especially if the person is not on Medicaid and significant impact in restrictions in 340B discounts. But a number of other manufacturers do not exempt FQHC.

A. Daniel Vigil: there is a hub showing availability of discount programs. Arguing for federal reform of 340B. This manufacturer does not apply its restrictions on contract pharmacies to FQHCs.

Q. Gui Woolston, CT DSS: Does Novartis have a position on state transparency legislation?

A. Daniel Vigil: Generally believes that improved transparency is helpful, although no specific position on the particular state statutes but generally supports that intent.

Q. Felipe Moreno, CHC, Inc.: For contract pharmacies for uninsured patients, the proximity matters significantly in order to enable meaningful access. Most of the pharmaceutical manufacturers have blocked access except to one contract pharmacy location for this FQHC's patients and restricts access. Trying to improve access for uninsured patients.

Q. Paul Kidwell, CT Hospital Association: Outside of the 340B program, significant discounts that pharmaceutical manufacturers provide to pharmacy benefit manufacturers.

A. Daniel Vigil, Novartis: Discounts for PBMs is distinct from 340B, although general challenges with PBMs influencing the 340B and commercial insurance discounts. General concerns about PBM tactics.

Sen. Heather Somers: Her question was already answered.

5. Other Discussion About Statutory Provisions in PA 23-171, sec. 16

Dr. Dalal briefly referenced the statutory provisions.

6. Process for Gathering Feedback from Workgroup Members and DSS Preparing Report

Dr. Dalal briefly summarized the process for workgroup members to submit written materials.

Heather Ferguson-Hull, OPM: Asking if there would be an opportunity for workgroup members to review the draft report.

Jennifer Herz, Boehringer Ingelheim: Asking for ability to have more time to submit written materials.

Dr. Dalal/Joel Norwood: Limited time to complete the report and limited ability to incorporate additional substantive information beyond the existing deadlines.

7. Other Business

There was no other business identified.

8. Adjourn

The meeting was adjourned.

The 340B Program: Current Environment in States

Connecticut 340B Drug Pricing Workgroup

November 7, 2023

NASHP | NATIONAL ACADEMY FOR STATE HEALTH POLICY

nashp.org

340B: Why It Matters to States

- As the program has grown so dramatically it accounts for a much larger share of the total drug purchasing
- As states act to lower pharmacy costs, they are addressing questions from covered entities who are protective of the financial value of 340B discounts
- As states look to increase access to treatment for low income and uninsured people, there is concern that drugs purchased with 340B discounts are not being used to benefit those patients
- States want to understand the connection between the growth of 340B and health system consolidation
- Growth of 340B has reduced Medicaid rebates and hampered state efforts to reduce drugs spending via pharmacy carve out

340B Discount Program

- Program is now over 30 years old – Enacted by Congress as part of the Veterans Health Care Act of 1992 (Public Law 102-585)
- Program provides mandatory discounts from drug manufacturers to “covered entities”
  - In order for manufacturers to participate in the Medicaid Drug Rebate Program, they must participate in 340B
- Intended to help providers serve low-income people: “to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”
- Federal administration of the program resides within the Office of Pharmacy Affairs of the Health Resources & Services Administration (HRSA).

Scope of the Original Program

- **Discounts:**
  - Minimum discounts – 23.1% of average manufacturer price but inflationary discounts result in price reductions up to 50%
  - Penny pricing – When the price of a drug increases faster than inflation, covered entities can sometimes acquire them for $0.01 per unit. Humira is an example
- **Original covered entities:**
  - Disproportionate Share Hospitals
  - Safety net providers such as Federally Qualified Health Centers (FQHCs), Ryan White Centers and Title X family planning clinics
- A covered entity without an in-house pharmacy was allowed to contract with ***a single outside pharmacy*** to provide drugs to patients

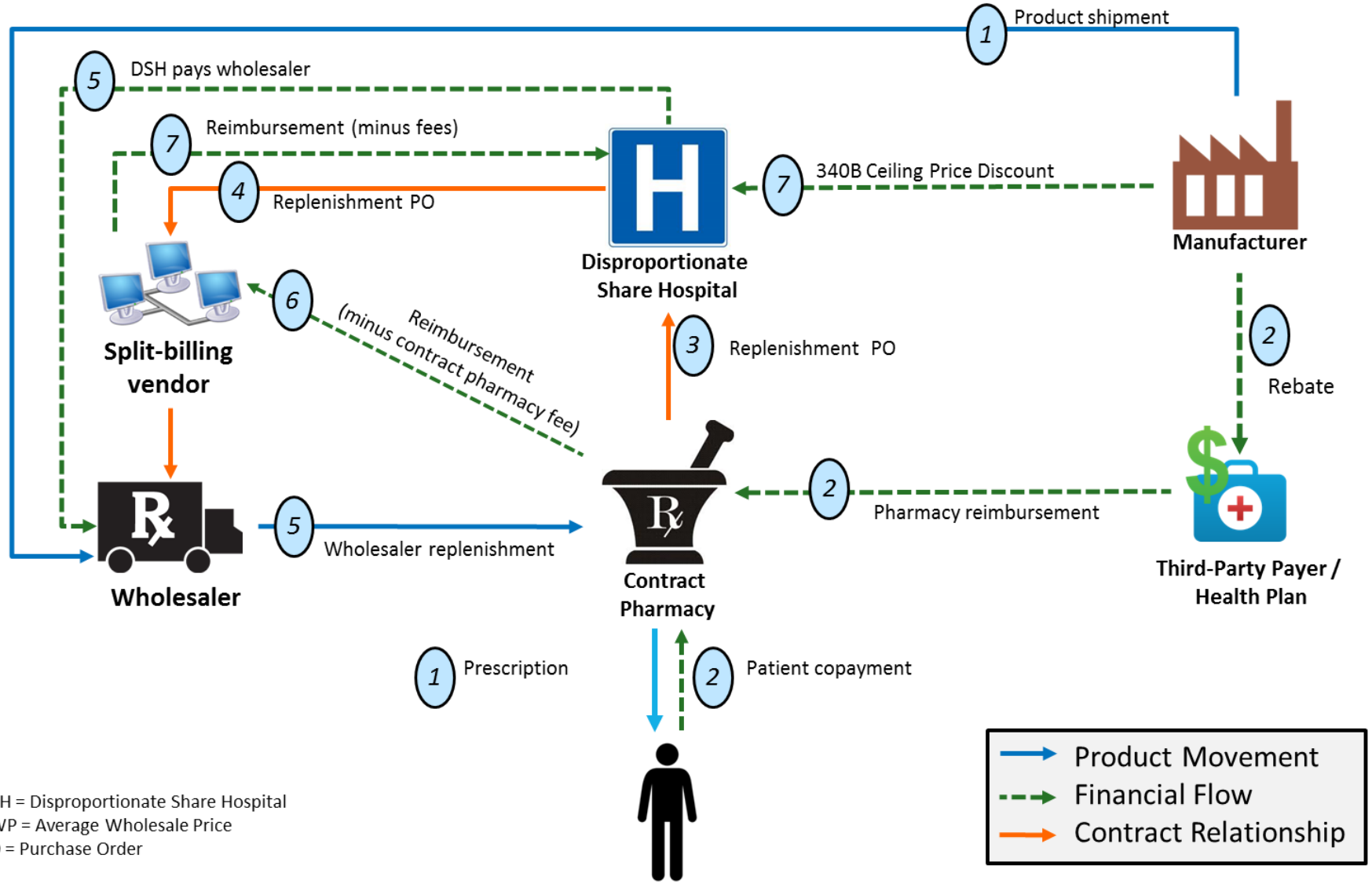
Changes to the Program

- Congress changed the law in 2006 and in 2010 (as part of the ACA), which in both instances resulted in expansion of the entities participating in the program
- Expansion of covered entities to include more hospitals
  - Critical access hospitals, sole community hospitals, stand alone cancer hospitals
  - Coverage of “child sites” – clinics and other facilities that exist outside of the four walls of a hospital but included in a hospital’s cost report
- Huge expansion in the availability of contract pharmacies
  - Any covered entity can use an unlimited number of contract pharmacies

Result of the Changes

- Dramatic increase in number of covered entities
  - The number of covered entities has ballooned from 8,100 in 2010 to approximately 50,000 in 2020
  - Prior to 2004 hospitals accounted for 10% of CEs, now account for over 60%
  - DSH Hospitals account for 78% of 340B sales
- Skyrocket in number of contract pharmacies
  - 1,300 in 2010 to over 30,000 in 2021
  - CVS, Walmart and Walgreens make up 58% of the contract pharmacy locations (even though the covered entities they contract with are required to be not for profit)

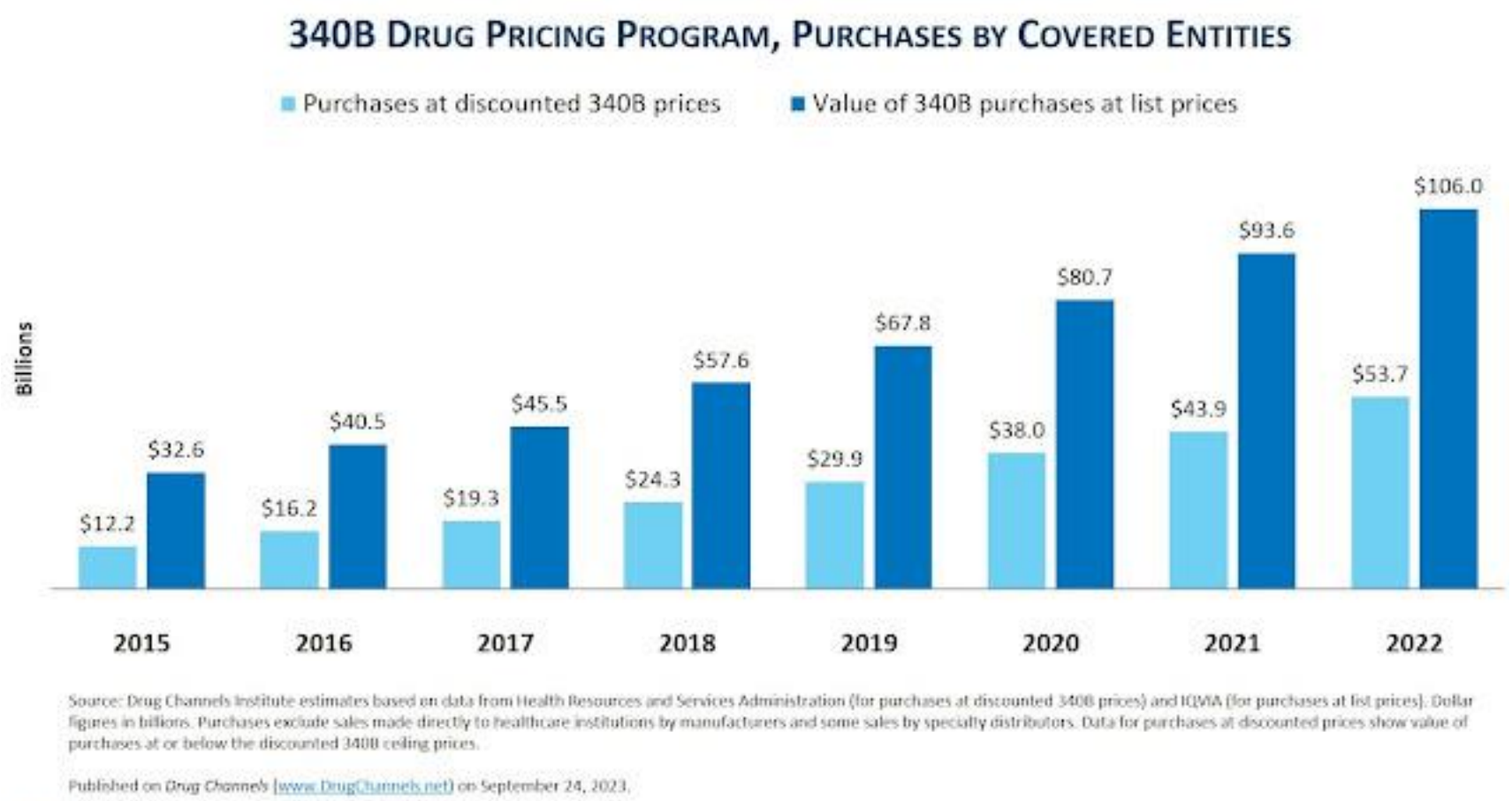
Flow of Funds & Products with Contract Pharmacies



DSH = Disproportionate Share Hospital
AWP = Average Wholesale Price
PO = Purchase Order

DRUG CHANNELS INSTITUTE

Impact of Growth - $$



Impact of Growth – Covered Entities

340B Drug Pricing Program, Purchases by Covered Entities, 2021

Entity type	Total 2021 purchases at 340B discounted prices	Share of total 2021 purchases	Change in total purchases vs. 2020
Hospital			
• Disproportionate Share Hospitals	$34,288,472,705	78.1%	+15.1%
• Children's Hospitals	$1,330,248,212	3.0%	+14.1%
• Rural Referral Centers	$1,174,151,155	2.7%	+34.8%
• Critical Access Hospitals	$620,923,559	1.4%	+18.6%
• Sole Community Hospitals	$451,594,319	1.0%	+11.2%
• Free-standing Cancer Centers	$304,098,033	0.7%	+35.6%
Subtotal	$38,169,487,983	86.9%	+15.7%
Federal Grantee			
• Consolidated Health Center Programs	$2,215,221,250	5.0%	+12.3%
• Ryan White HIV/AIDS Program Grantees	$2,180,003,882	5.0%	+8.2%
• Sexually Transmitted Disease Clinics	$871,036,833	2.0%	+54.2%
• Comprehensive Hemophilia Treatment Center	$192,106,843	0.4%	-10.1%
• All other	$284,557,390	0.6%	+20.6%
Subtotal	$5,742,926,198	13.1%	+14.8%
Total	$43,912,414,181	100.0%	+15.6%

Source: Drug Channels Institute analysis of data from Health Resources and Services Administration. Purchases exclude sales made directly to healthcare institutions by manufacturers and some sales by specialty distributors. Data for purchases at discounted prices show value of purchases at or below the discounted 340B ceiling prices.

Published on *Drug Channels* (www.DrugChannels.net) on August 15, 2022.

DRUG CHANNELS INSTITUTE

- Hospitals account for 86.9% of program purchases
- Other grantees make up 13.1% of program purchases

State Activity to Date – PBMS and Manufacturers

- As 340B has grown, health care purchasers (commercial insurers, PBMs, TPA, ERISA plans) have attempted to account for and capture the value of these deep discounts in the purchasing practices and negotiations with hospitals, clinics and covered entities
- 28 states have enacted some form of “anti-discrimination” legislation, prohibiting PBMS and others from
  - Reimbursing covered entities/contract pharmacies at a lower rate
  - Charging fees to covered entities/contract pharmacies
  - Making sure that consumers are not restricted in using contract pharmacies
- Louisiana and Arkansas have enacted legislation prohibiting drug manufacturers from restricting access to 340B drugs at contract pharmacies – Laws being challenged in federal court by PhRMA

State Activity to Date – Transparency

- In 2023, for the first time, states enacted transparency legislation to try to understand the value of 340B within their state and how those dollars were being utilized
- In addition to the bill that moved forward in Connecticut, three states passed legislation that required some level of reporting by 340B Covered entities
  - **Maine** – Beginning in 2024, Hospitals must report 1) annual estimated savings from 340B; 2) a comparison of the hospital's estimated savings under 340B to the hospital's total drug expenditures, including examples of the hospital's top drugs; and 3) a description of how the hospital uses savings from the 340B program for the community benefit
  - **Minnesota** – Beginning in 2024, all covered entities must report aggregate information on drug acquisition costs, reimbursement received and payments to contract pharmacies; hospitals must report this information for their top 50 drugs
  - **Washington** - HCA must "establish an annual reporting requirement for all covered entities participating in the 340B drug pricing program that received Medicaid funds"

Side by Side Comparison of Enacted 340B Transparency Laws

	Washington	Minnesota	Maine
Covered Entities Impacted	All 340B covered entities that participate in Medicaid	All covered entities, but hospitals have additional reporting responsibilities	Hospitals only
Implementing Agency	Washington Health Care Authority	Minnesota Department of Health	Maine Health Data Organization (Maine's APCD)
Data required to be reported	Undefined – HCA must "establish an annual reporting requirement for all covered entities participating in the 340B drug pricing program that received Medicaid funds"	1. Aggregate acquisition cost for drugs 2. Aggregate payments received for drugs dispensed to patients 3. Aggregate payments from covered entity to contract pharmacies 4. Information must be reported by payer type 5. For hospitals only, the 50 most frequently dispensed drugs	1. A description of how the hospital uses savings from the 340B program for the community benefit, including services that could not continue absent 340B savings 2. annual estimated savings from the 340B program to the hospital, comparing the acquisition price of drugs under the 340B program to group purchasing organization pricing 3. A comparison of the hospital's estimated savings under the 340B program to the hospital's total drug expenditures, including examples of the hospital's top drugs purchased through the 340B program 4. A description of the hospital's internal review and oversight of the 340B program
Reporting schedule	Annually, with no defined start date	Annually, beginning on November 15, 2024	Annually, beginning on January 1, 2024
Is reporting public?	Not specified	Data specifically classified as "nonpublic"	MHDO will post each report on the MHDO website and will also create a report summarizing the hospital data and post the report publicly
Citation to Statute	ESSB 5187, §211(32)(b)	Minn. Stat. § 62J.312, sub.6	22 MRSA §1728

NASHP
NATIONAL ACADEMY FOR STATE HEALTH POLICY

The 340B Drug Discount Program:
What is it? How does it work? Why is it a policy problem?

William Smith, PhD
Senior Fellow in Life Sciences
Pioneer Institute

Robert Popovian, Pharm.D., MS
Senior Visiting Health Policy Fellow
Pioneer Institute

Gauri Binoy
Research Assistant in Life Sciences Initiative
Pioneer Institute

Michael Walker
Senior Fellow, Pioneer Analytics
DataMadeUseful, LLC

Briefing Connecticut 340B Workgroup
November 28, 2023

340B: What is it?

In 1990, Congress passed OBRA '90, requiring drug manufacturers to provide Medicaid with the lowest price of any payer

This created a problem for hospitals and clinics serving low-income areas as drug manufacturers were voluntarily giving them the lowest prices in the nation, prices that might not have continued if they were required to be passed on to Medicaid

In 1992, Congress created the 340B program requiring manufacturers to provide deep discounts to hospitals and clinics serving low-income patients and exempting these prices from OBRA best price rules

Facilities became eligible for 340B discounts if 11.75% of their patients were Medicaid

340B: How does it work?

Medicare Patient

- Hospital purchases oncology drug at discounted price of $25,000 for a medicine with a list price of $100,000. Dispenses to Medicare patient. Bills Medicare at 106% of Average Sales Price, or $95,000. Hospital profit: $70,000

Patient with Commercial Insurance

- Hospital purchases oncology drugs at discounted price of $25,000. Dispenses to commercially-insured patient. Bills health plan at 75% of list price ($75,000), the plan's negotiated rate. Hospital profit: $50,000.

Uninsured Patient

- Hospital purchases oncology drug at discounted price of $25,000 for a medicine with a list price of $100,000. Cost to uninsured patient is (hopefully) $25,000. Hospital profit: $0. Patient may use manufacturer assistance program.

340B: Why is it a policy problem?

Incentive to Arbitrage Discounts with *Insured* Populations: $40 billion in hospital profits in 2019

Massive takeovers of community-based physician practices in higher income areas

Uncontrolled growth: in 2022, $53.7 billion in discounted purchases or $106 billion at list prices. By 2026, largest federal drug program

For-profit PBMs and pharmacies dominating program: 32,000 pharmacies with 75% at CVS, Walgreens, Express Scripts, Optum, Walmart

10,000 covered entities versus 550 in 1990s. Growth comes as Medicaid/ACA has expanded and uninsured population dropped from 48.2 million in 2010 to 30 million in 2020

Decline in provision of charity care: NEJM says charity care became more difficult to obtain after 340B growth. AHA: total uncompensated care fell to 25-year lows in 2015 and 2016

340B Growth

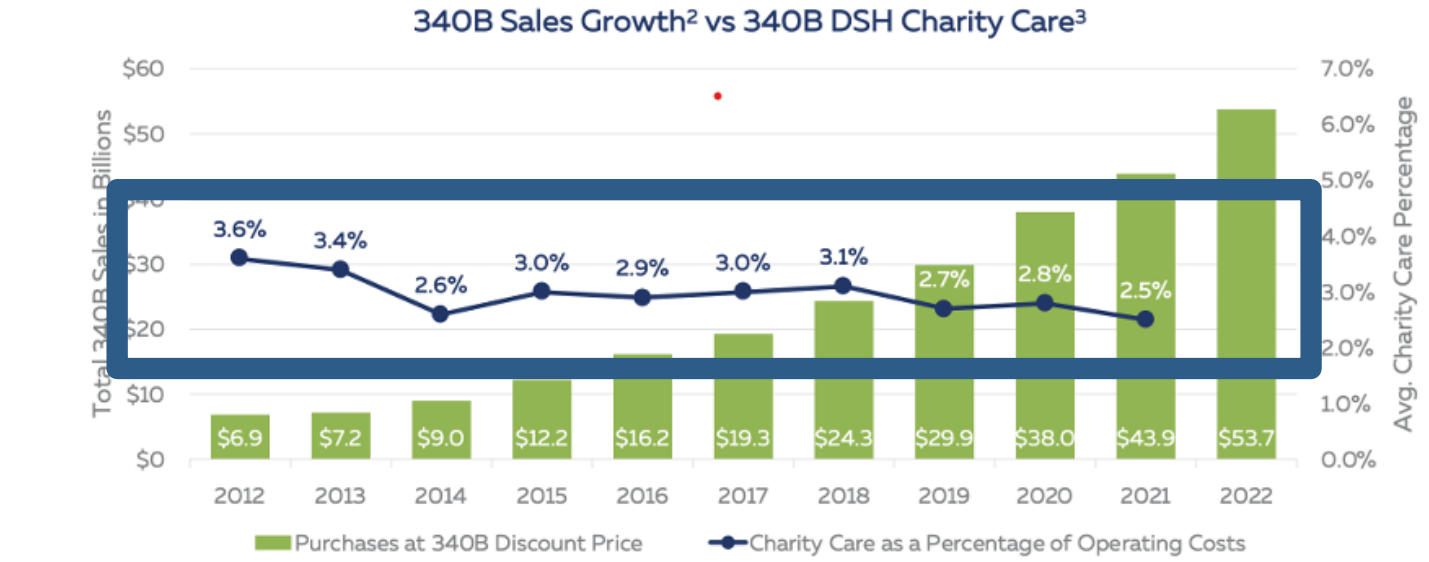
The 340B Program Reached $54 Billion in 2022, increasing 22% from 2021

340B Sales Growth vs 340B DSH Charity Care

340B DSH Charity versus 340B Sales Growth

340B DSH Charity Care is Again Trending Downwards

The 340B program has grown from $6.9 billion in discounted sales in 2012 to nearly $54 billion in discounted sales.[1] However, charity care for 340B DSH hospitals has decreased since 2018.



1. Fein AJ; Drug Channels Institute. EXCLUSIVE: The 340B Program Reached $54 Billion in 2022 – up 22% vs. 2021. Published September 2023. Accessed September 2023. https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.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.

https://340breform.org/wp-content/uploads/2023/10/2023-Charity-Care-Report-Final-1.pdf

DSH 340B Charity Care Provision

69% of 340B DSH hospitals provide charity care at rates lower than the national average.

36% of 340B DSH hospitals provide charity care that represents less than 1% of their total operating costs in 2021

A 25% of 340B DSH hospitals account for 80% of the charity care provided by all 340B hospitals in 2021

Non-340B short-term acute care hospitals in the United States have equal charity care (2.6%) compared to 340B DSH hospitals (2.5%)

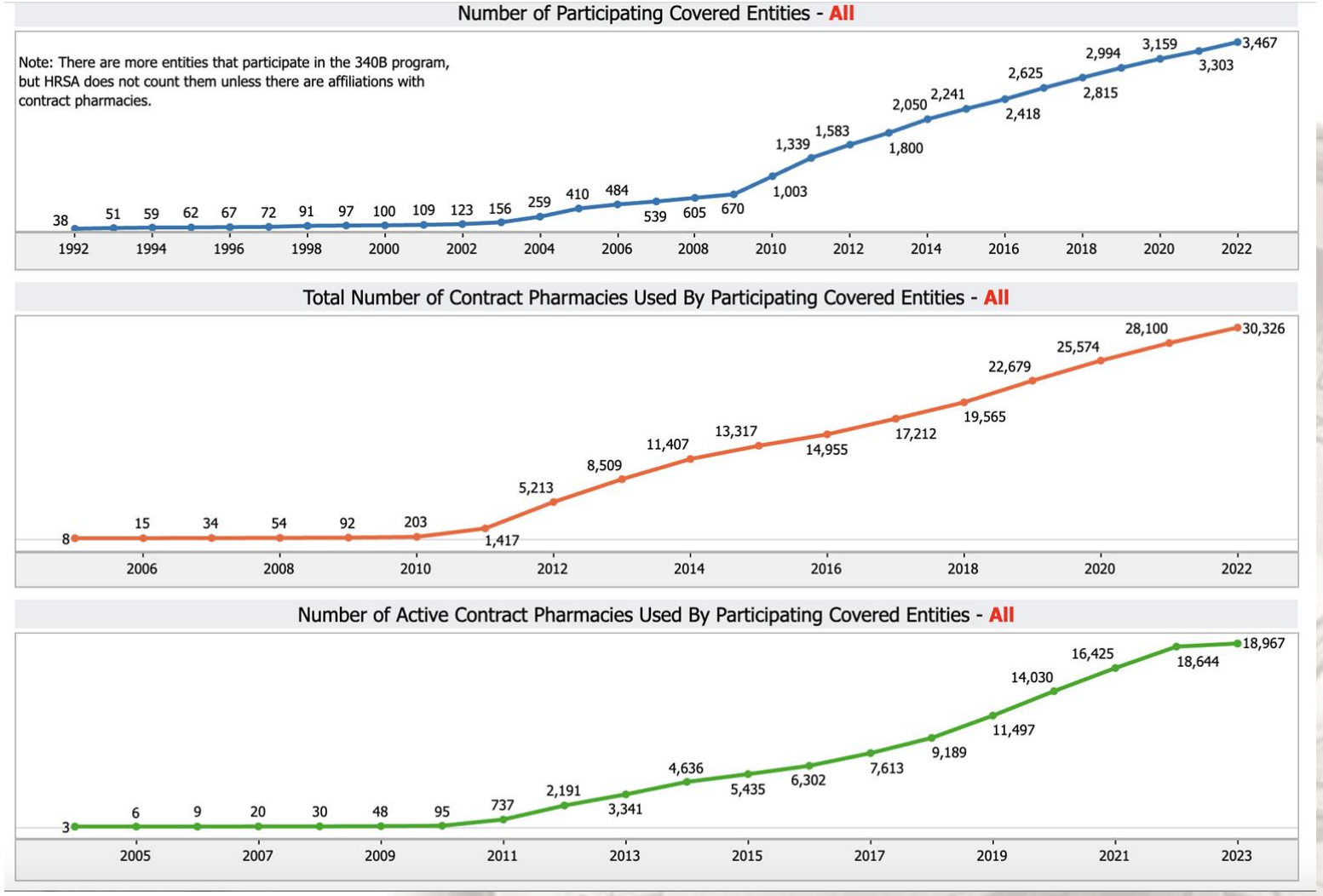
https://340breform.org/wp-content/uploads/2023/10/2023-Charity-Care-Report-Final-1.pdf

Pioneer Institute 340B Web Tool

Two additions to the tool: Charity Care + Legislative Mapping

Trend Data

Covered Entities and Pharmacies 1992-2012

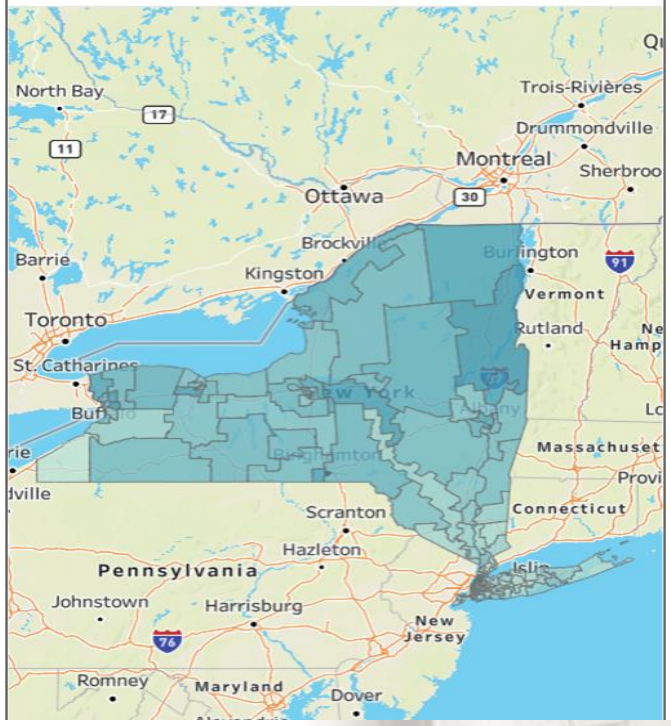


District-Based Mapping

Number of Hospitals, Health Centers, and Contract Pharmacies by District

340B Drug Pricing Program
Legislative District Search

New York Lower House Districts
Hover over a districts to see the number of pharmacies, hospitals, and health centers.

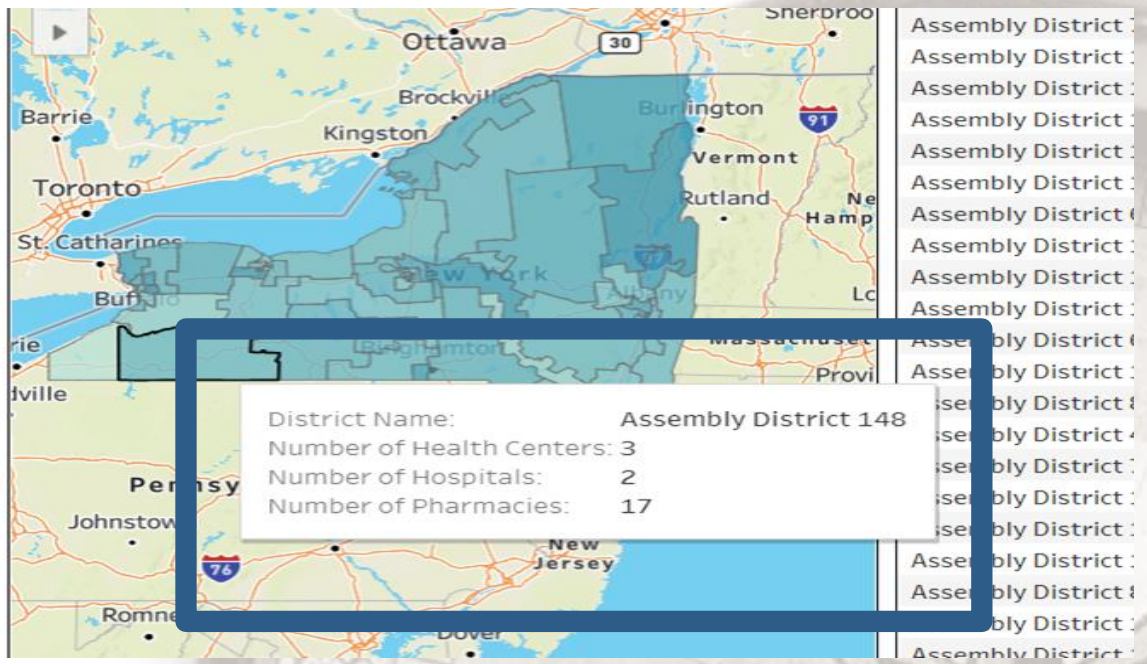


New York -Ranked by Pharmacies in District

District Name	Number of Phar..	Number of Hospitals	Number of Health Cent..
Grand Total	2,121	102	358
Assembly District 84	47	1	13
Assembly District 75	33	0	7
Assembly District 143	29	0	0
Assembly District 114	28	1	18
Assembly District 79	27	1	12
Assembly District 146	26	0	0
Assembly District 138	26	2	1
Assembly District 122	26	1	0
Assembly District 123	25	2	2
Assembly District 113	25	1	6
Assembly District 65	24	0	5
Assembly District 145	24	2	0
Assembly District 115	24	3	5
Assembly District 110	24	0	0
Assembly District 68	23	2	9
Assembly District 127	23	0	0
Assembly District 80	22	1	1
Assembly District 46	22	0	1
Assembly District 70	21	1	5
Assembly District 140	21	0	1
Assembly District 118	21	1	1
Assembly District 116	21	4	3
Assembly District 86	20	0	13
Assembly District 139	20	1	8
Assembly District 109	20	1	1

District-Based Mapping

Number of Hospitals, Health Centers, and Contract Pharmacies by District



District-Based Mapping

Name & Location of Contract Pharmacies by District

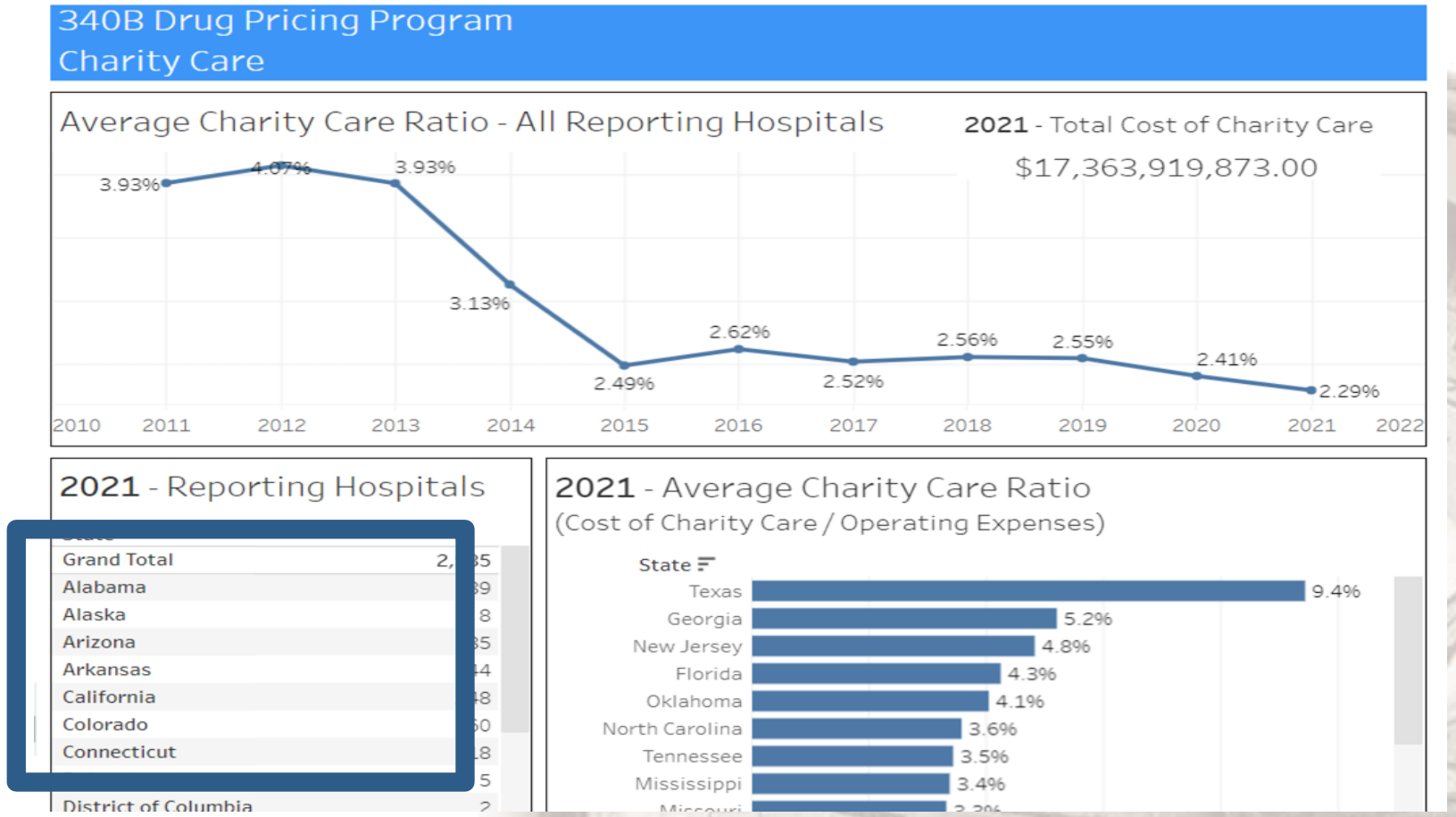
340B Drug Pricing Program
Legislative District Search

Pharmacy Address - Lower House Disticts: State: **NY**, City: **All**

Lower House District	Pharmacy Name	Pharmacy Address	Pharmacy City	Total Contracts
Grand Total				40
Assembly District 148				2
	ECKERD CORPORATION	12208 N.Y. STATE ROUTE 16	YORKSHIRE	1
	WALGREEN EASTERN CO., INC.	3242 ROUTE 39	YORKSHIRE	2
	FILLMORE & FISHER PHCY	2 CENTER ST	CUBA	3
	FILLMORE AND FISHER PHARMA..	10560 ROUTE 19	FILLMORE	3
	BARTHOLOMEWS PHARMACY INC	2 ELM ST	FRANKLINVILLE	1
	MARKS, JEFFREY A.	9 WEST MAIN ST.	FRIENDSHIP	1
	CVS ALBANY, L.L.C.	415 N. UNION ST.	OLEAN	7
	DANIEL J HORN	111 E GREEN ST	OLEAN	4
	ECKERD CORPORATION	265 NORTH UNION STREET	OLEAN	2
	WAL-MART PHARMACY 10-2159	1869 PLAZA DR	OLEAN	4
	RITE AID OF NEW YORK, INC.	9 BROAD STREET	SALAMANCA	1
	NICHOLSON PHARMACY INC.	36 SCHUYLER ST	BELMONT	1
	FILLMORE & FISHERS PHARMAC..	138 N MAIN ST	WELLSVILLE	1
	WALGREEN EASTERN CO.	10 N. MAIN ST.	WELLSVILLE	2
	WALGREEN EASTERN CO., INC.	4175 STATE ROUTE 417	WELLSVILLE	4
	WORTHY PHARMACY, LLC	202 MAIN ST	OLEAN	1

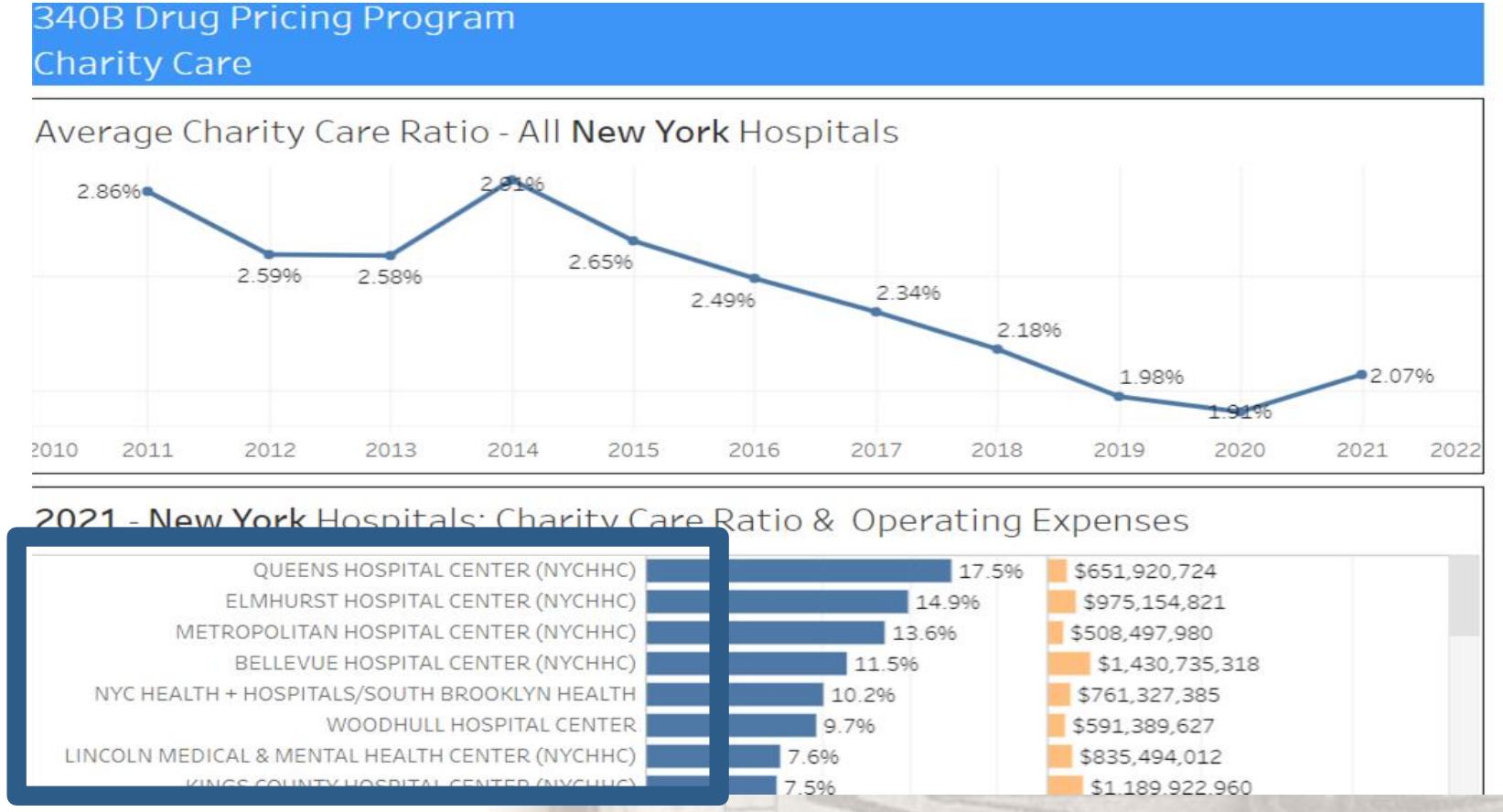
Charity Care

Can Select for Charity Care at the State Level

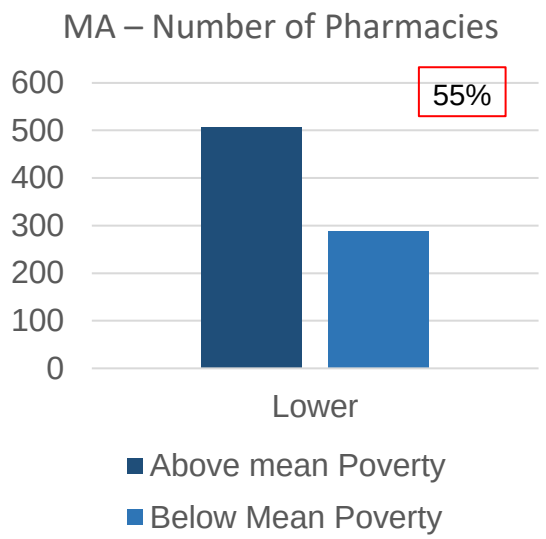


Charity Care

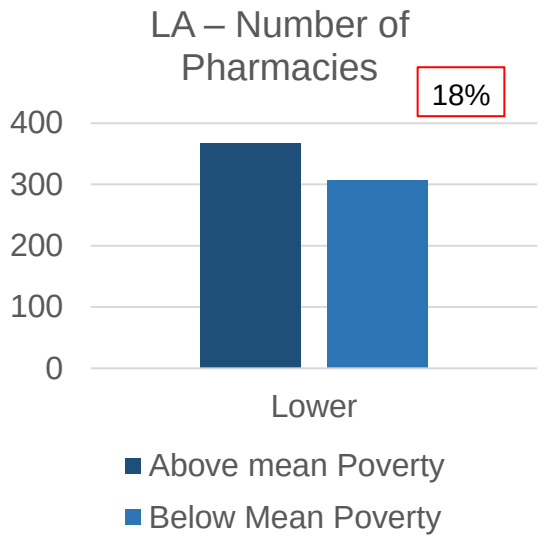
Can Select for Hospitals within the State Level



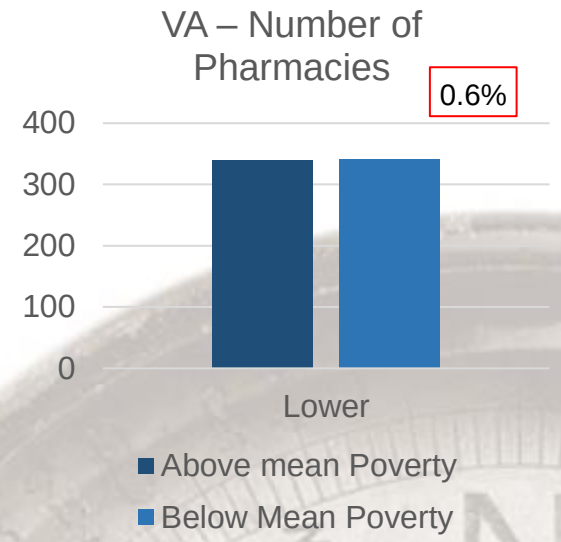
10.4% of the population living in poverty



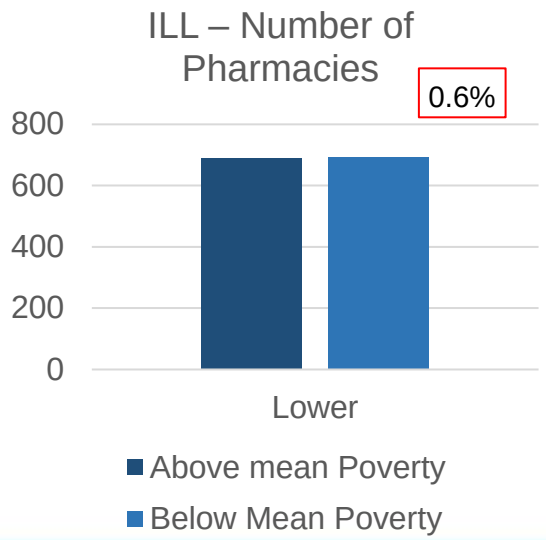
18.6% of the population living in poverty



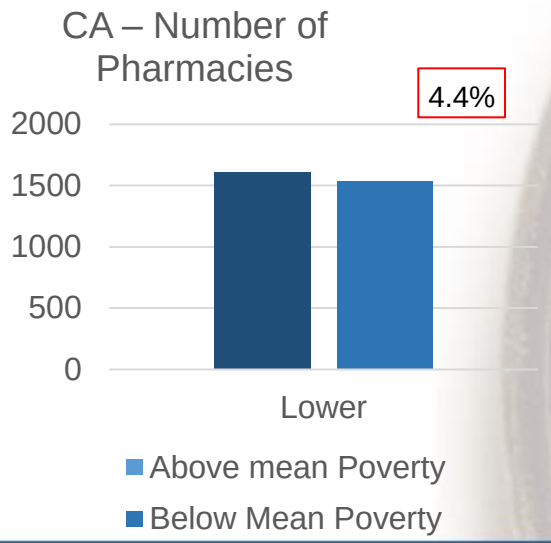
10.6% of the population living in poverty



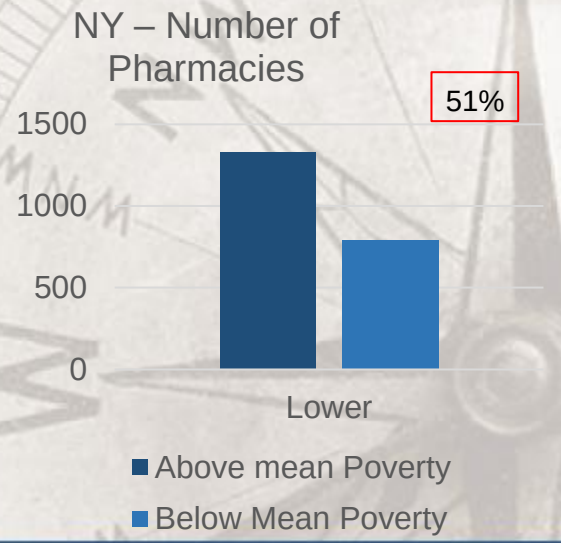
11.9% of the population living in poverty



12.2% of the population living in poverty



14.3% of the population living in poverty



What Can States Do to Reform a Federal Program?

The Problem

1. Uncontrolled program and revenue growth while charity care declines
2. Wealthier areas *tend to be* over served by the 340B program and lose income areas tend to be underserved.22

The Solution

1. States may be able to require that 340B covered entities disclose 340B revenue and charity care spending
2. Utilize Pioneer's 340B web tool to find overserved and underserved areas in your states and hold hearings.

Contact Information and Web Tool Address

Web Tool Address: https://pioneerinstitute.org/340babuse/

William S. Smith
Senior Fellow on Life Sciences | Pioneer Institute
wsmith@pioneerinstitute.org
Office: (617) 723-2277 | Mobile: (202) 570-6968

@PioneerBoston

PioneerInstitute.org

@PioneerInstitute

PIONEER HEALTH

340B Drug Discounts:
An Increasingly Dysfunctional Federal Program

By William Smith and Josh Archambault

WHITE PAPER
No. 248 | March 2022

PIONEER INSTITUTE
PUBLIC POLICY RESEARCH

MISSION

Pioneer Institute develops and communicates dynamic ideas that advance prosperity and a vibrant civic life in Massachusetts and beyond.

Vision

Success for Pioneer is when the citizens of our state and nation prosper and our society thrives because we enjoy world-class options in education, healthcare, transportation and economic opportunity, and when our government is limited, accountable and transparent.

Values

Pioneer believes that America is at its best when our citizenry is well-educated, committed to liberty, personal responsibility, and free enterprise, and both willing and able to test their beliefs based on facts and the free exchange of ideas.

PIONEER HEALTH

This paper is a publication of Pioneer Health, which seeks to refocus the Massachusetts conversation about health care costs away from government-imposed interventions, toward market-based reforms. Current initiatives include driving public discourse on Medicaid; presenting a strong consumer perspective as the state considers a dramatic overhaul of the health care payment process; and supporting thoughtful tort reforms.

PIONEER TRANSPORTATION

Pioneer Transportation seeks reforms that allow commuters to take full advantage of the coming mobility revolution — with access to a range of affordable and on-demand public and private transportation options, as well as transit-friendly real estate development.

PIONEER OPPORTUNITY

Pioneer Opportunity seeks to keep Massachusetts competitive by promoting a healthy business climate, transparent regulation, small business creation in urban areas and sound environmental and development policy. Current initiatives promote market reforms to increase the supply of affordable housing, reduce the cost of doing business, and revitalize urban areas.

PIONEER EDUCATION

Pioneer Education seeks to increase the education options available to parents and students, drive system-wide reform, and ensure accountability in public education. The Center's work builds on Pioneer's legacy as a recognized leader in the charter public school movement, and as a champion of greater academic rigor in Massachusetts' elementary and secondary schools. Current initiatives promote choice and competition, school-based management, and enhanced academic performance in public schools.

Table of Contents

Introduction

The 340B program requires drug companies to provide certain hospitals and clinics with drugs at significant discounts. The Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services, manages the program through its Office of Pharmacy Affairs. The program was established in 1992; hospitals and clinics were eligible to participate if they treated a certain percentage of Medicaid patients, which was thought to be a proxy for identifying entities that treated low-income uninsured patients. After its first decade, the program has undergone significant and likely unforeseen growth.

Significant Program Growth & Mission Drift

340B began as a worthy, targeted program that offered discounts to the low-income uninsured. Savings from these drug discounts also could be used, as HRSA describes it, to provide "comprehensive services" to vulnerable populations.[1] At first, 340B largely fulfilled this mission. During its first 13 years, the program grew slowly, and by 2005 there were only 583 participating hospitals.[2]

Due to changes in the Affordable Care Act (ACA) that created incentives for hospitals to participate in the program, by 2019 the program had exploded in size and included more than 2500 hospitals with drug purchases totaling $30 billion, accounting for 8 percent of all U.S. prescriptions.[3] Since 340B participation is contingent upon the number of Medicaid patients that are treated, the vast expansion of Medicaid enrollment under the ACA allowed many more hospitals to become eligible for the program.

The 340B program would be difficult to criticize if the huge revenues from billions in drug sales were being used exclusively to assist low-income uninsured populations. But the data actually suggest that, as the program has grown exponentially, these populations are being helped less and less.

One estimate from the Berkeley Research Group projects that by 2026, 340B will be the largest federal drug program, eclipsing gross drug sales of both the Medicare and Medicaid drug programs.[4] More specifically, as the number of 340B sites expanded to 30,000 between 2009 and 2015, there should have been significant improvement in low-income patients' ability to afford their prescription drugs. But the opposite seems to have happened: at a time of explosive growth in 340B, it became significantly more difficult for low-income populations to afford prescription drugs.

At a time of explosive growth in 340B, it became significantly more difficult for low-income populations to afford prescription drugs.

It is now difficult to characterize 340B as a program with the primary mission of providing low-income, uninsured patients with discounts on drugs, nor is it clear that the bulk of "savings" from the 340B program are channeled to "comprehensive services" for vulnerable populations. Many hospitals now use the program as for-profit retail arbitrager might, buying drugs at a low price through the 340B program and then reselling them to government and commercial payers at much higher prices. Many hospitals have discovered this profitable tactic, and their revenues from the program are soaring, not only at the expense of pharmaceutical companies, but with little benefit for those the program was designed to help. The irony is that a program that was intended to reduce drug costs for lower income populations now displays overwhelming incentives not only to prescribe more drugs, but also to prescribe more expensive drugs as hospitals generate more revenue from pocketing the spread on costlier drugs.

The hospitals have been creative in adopting arbitrage to drive their revenues, and there is significant evidence that the original mission of the 340B program—drug discounts and other services for the low-income uninsured—has taken a back seat to revenue generation. One recent study concluded that, with its significant recent expansion, the 340B program generated $40 billion in profits during 2019 for hospitals, pharmacies, "and possibly patients (in the form of reduced-price medicines)."[5]

The hospitals have expanded in significant ways to capitalize on this revenue opportunity. There is considerable evidence that the 340B program has caused hospitals to acquire community-based physician practices, such as oncology practices, in affluent areas.[6] When hospitals are able to capture wealthy patients through these satellite offices, their arbitrage is more effective since

the hospital can resell a 340B drug to a wealthy patient's commercial health plan or Medicare and then pocket the significant spread between the 340B price and the health plan reimbursement. According to the Government Accountability Office (GAO), "about three quarters of the approximately 37,500 covered entity sites participating in the program are affiliated with hospitals."[7] It is unclear how the purchase of physician practices in affluent communities represents the expansion of "comprehensive services" to vulnerable populations.

The hospitals do not see it that way. They point to the many genuinely worthy programs they support and claim that these programs would not be possible without the 340B program. For example, 340B Health, the lobbying group for the hospitals, put out a press release late last year arguing that essential programs for low-income patients were being funded by the 340B program: "340B savings from drug company discounts go toward effective programs that are tailored to the needs of patients with low incomes and those who live in rural parts of our country. The fact that 340B accomplishes all this without relying on taxpayer dollars is a significant accomplishment."

Interestingly, the press release does not highlight the hospitals' success in passing along 340B drug discounts to uninsured patients, it simply highlights "programs" that do not have budget figures associated with them. Also, there is a mischaracterization of the revenues obtained through arbitraging the 340B discounts, which are described as "savings," not as revenue. The release goes on to describe some of those programs: "One hospital might provide home visits for heart failure patients, while another might integrate pharmacy support into hepatitis C care teams, while yet another might connect low-income HIV/AIDS patients with housing assistance."[8]

When these programs are described in this anecdotal fashion, there is little accounting as to whether, as revenues from the 340B program exploded, the growth of those "comprehensive services" corresponded with that of 340B revenues. Anecdotes about admittedly worthy programs managed by these hospitals do not provide an accounting of how specific 340B revenues fund a variety of "comprehensive services" that cost the equivalent of those 340B revenues.

Without an accounting of how this growing 340B revenue is being spent, we cannot verify whether the "comprehensive services" offered to vulnerable populations have expanded at the same rate as the hospitals' 340B revenue. In fact, there is some evidence that, as 340B revenue has expanded exponentially, services provided to vulnerable populations have declined. One recent study concluded that "it is evident that the ability of people suffering severe economic hardship to afford needed medicines and medical care, relative to the general population, is negatively correlated with growth in the 340B program."[9]

Another set of players that are now profiting from the 340B program are massive for-profit pharmacy chains. In 1996, HRSA provided guidance to hospitals that 340B drugs could only be dispensed through the hospital's in-house pharmacy or a single external contract pharmacy. In 2010, HRSA revised that guidance to allow hospitals to use an unlimited number of contract pharmacies.

Early in the program, the number of participating pharmacies could be counted in the hundreds, but 30,000 pharmacies now participate. Many of these are highly profitable chains such as CVS and Walgreens. Between June 2020 and June 2021, the number of participating pharmacies grew by an astonishing 2000.[10] Given the desire of hospitals to arbitrage 340B drugs and resell as many as possible, the growth in pharmacy participation is understandable. And, in order to drive sales, 340B hospitals make it profitable for pharmacies to participate. As the well-respected drug policy blog *Drug Channels* describes pharmacy profits in 340B: "These profits are much higher than a pharmacy's typical gross profit from a third-party payer—especially when a 340B entity shares a portion of its 340B earnings with the pharmacy."[11]

Unfortunately, the story of the 340B program is one that is all too common inside the Beltway: congressional policy makers develop a program to meet a genuine unmet need of low-income people, in this case making their drugs more affordable. However, the program is then designed in such a way that it is the vendors implementing it that benefit more than the low-income people the program was intended to help. Despite the program's obvious shortcomings, those vendors form a lobbying coalition that succeeds in expanding the program, making it even more profitable for the vendors, while the low-income uninsured fall even further behind. In the case of 340B, the

Due to changes in the Affordable Care Act (ACA) that created incentives for hospitals to participate in the program, by 2019 the program had exploded in size and included more than 2500 hospitals with drug purchases totaling $30 billion, accounting for 8 percent of all U.S. pre-scriptions.

program expanded to maximize the arbitrage of drug discounts to drive hospital revenues, not to expand services for the low-income or provide them with drug discounts.

Most unfortunately, the tens of thousands of hospitals and pharmacies that now benefit from the arbitrage of 340B discounts are a powerful lobby, so the prospects of reform are uncertain. As prominent local employers in many congressional districts, the 340B hospitals are certainly a more powerful lobby than low-income uninsured patients. In fact, 340B Health, an advocacy group for the program, sends out lists of 340B hospitals in each state and provides the corresponding member of Congress for each hospital.[12]

A Dubious Legislative Construction

The statute that created the 340B program is one of the most poorly constructed federal statutes of recent decades. Section 340B of 42 U.S. Code, is titled, "Limitation on prices of drugs purchased by covered entities." The lion's share of the statute is devoted to the level of drug discounts that must be provided by manufacturers to hospitals and clinics and how the government can check on the compliance of those participating in the program, especially the manufacturers. The statute does contain a lengthy definition of "covered entities" that can access these discounts, i.e., hospitals and clinics. But one must ***infer*** from this list of covered entities that the program is intended to help lower-income and uninsured populations because the entities listed in the statute serve a disproportionate share of this vulnerable population.

The infirmities in the statute are considerable. It does not define which patients should be eligible for drug discounts, making it possible for hospitals to prescribe 340B drugs to wealthy, commercially-insured patients. The statute does not require that savings and revenue from the program be devoted to programs that serve vulnerable populations. As we have seen from the legislative history, but not the statute, Congress did expect the program to fund "comprehensive services" for vulnerable populations, but there is no requirement that 340B revenues be devoted to such services. Moreover, those "services" are never defined. Again, one can infer from the statute that the common denominator of the "covered entities" that are permitted to participate in the program are that they serve lower-income uninsured populations, and therefore any "services" funded by the 340B program should be devoted to these populations—but this is only an inference, not a requirement. Finally, there is no requirement that the "covered entities" that participate in the program be located in areas that serve a high percentage of vulnerable patients. One would think that the statute would have been constructed to enroll 340B entities that would make it more likely that patients who sought emergency care at a 340B entity would be low-income and uninsured. As we have seen, as the program has grown, 340B entities are now less likely to be located in a medically underserved area.

The statute does not require that savings and revenue from the program be devoted to programs that serve vulnerable populations.

In short, the only thing the 340B statute requires is this: drug manufacturers must provide substantial discounts to certain hospitals and clinics. It is no wonder that hospitals soon learned that they could arbitrage these discounts by treating wealthier and well-insured patients and that maximizing revenue, and not charity care, became the primary goal of many hospitals participating in the program.

340B Growth and Trends in Charity Care

A key question for the 340B program is whether the exponential growth in revenues for hospitals and clinics has led to a similar increase in the level of charity care provided to low-income uninsured patients. More specifically, can policymakers have a high degree of confidence that the vast majority of this new revenue has been devoted to drug discounts for vulnerable populations as well as improved programs and services for that population.

The enactment of the Affordable Care Act (ACA) made it likely that more patients would be entering hospitals with some form of health insurance. The combination of the ACA and the growth of the 340B programs should have increased healthcare access to low-income populations

exponentially. The general consensus of the research is that, in the period after enactment of the ACA and the explosive growth in 340B, discounted drugs and community health services were ***more*** difficult to obtain. One study from the *New England Journal of Medicine* indicated that, in certain specialty areas the growth of the 340B program has not helped vulnerable populations: "Financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients.[13] One Avalere study commissioned by the drug industry concluded that, "In total, 63% of 340B hospitals provide less charity care than the national average for all short-term acute care hospitals, including for-profit hospitals."[14]

The general consensus of the research is that, in the period after enactment of the ACA and the explosive growth in 340B, discounted drugs and community health services were more difficult to obtain.

The central problem in arriving at a definitive conclusion about this important question is related to the statutory language of 340B: there is no adequate definition of the services for low-income patients that the law seeks to improve. The 1992 House report issued along with the 340B legislation simply states that the program was created, "to enable [covered] entities to stretch Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[15] The Affordable Care Act added a new requirement that hospitals must conduct an assessment of the community's needs and promulgate policies related to charity care, but there is no requirement that these entities offer a certain level of charity care relative to 340B income or expenses.[16]

While the congressional intent of the statute is that 340B revenues support safety-net care for vulnerable populations, there is ***no*** requirement in the law that 340B revenue be used in this way. A 2009 law required that hospitals report their "community spending" to the IRS, "broken out for charity care, the cost of unreimbursed Medicaid care and community improvement programs."[17]

In fact, there is some evidence that, as 340B revenue increased, charity care provided by non-profit hospitals may have declined. The first indication that the program may not be serving the most vulnerable populations began to appear after 2004, when data became available suggesting that 340B hospitals were increasingly located in areas where fewer vulnerable patients could be found. As the program expanded after 2004, fewer large, public hospitals were enrolled in the program. One University of Southern California study concluded, "These results suggest that hospitals that began participating in the 340B program after 2004 are more likely to serve wealthier and more insured populations, which is counter to the original intent of 340B savings being used to support care for vulnerable populations.[18] This USC study's conclusions seemed corroborated by another recent study that concluded, "a dismal 38% of 340B disproportionate share hospitals (DSH) are located in medically underserved areas (MUAs) as defined by the Health Resources and Services Administration, despite their mission of 'serving a significantly disproportionate number of low-income patients.'"[19]

In fact, there is some evidence that, as 340B revenue increased, charity care provided by non-profit hospitals may have declined.

In addition, the data indicate that the rapid expansion of the 340B program brought in hospitals that provided less charity care. "These post-2010 participants tend to be smaller and provide little more uncompensated care than nonparticipants. Most importantly, they tend to take efforts to increase their DSH patient percentages to the minimum level to qualify for the program and no further."[20] In other words, these hospitals draw in Medicaid patients to meet the 340B eligibility requirements and, once they are enrolled in the program, make little effort to expand services for low-income patients.

According to data from the American Hospital Association: "Total uncompensated care fell to a 25 year low in 2015 and held steady in 2016."[21] Another study in the *Journal of the American Medical Association* found that the wealthiest nonprofit hospitals provided "disproportionately low levels of charity care."[22] That same study indicated that the Affordable Care Act's expansion of Medicaid eligibility in many states caused nonprofit hospitals in those states to provide "less charity care than hospitals in other states."

The most troubling recent report about charity care and nonprofit hospitals was published in *Health Affairs* in April of 2021. This large study considered charity care data on 4,666 acute care hospitals (1024 government, 2709 nonprofit and 930 for-profit). That report concluded that nonprofit hospitals spend less on charity care than government or for-profit hospitals. Using 2018 data from Medicare Hospital Cost Reports, the study concluded that, "in aggregate, nonprofit

hospitals spent $2.3 of every $100 in total expenses incurred on charity care, which was less than government hospitals, ($4.1) or for-profit ($3.8) hospitals."[23]

Shockingly, the report seems to conclude that the government may wish to revisit the generous tax treatment of nonprofit hospitals, which is predicated upon obligations to provide more charity care than for-profit hospitals. "These results suggest that many government and nonprofit hospitals' charity care provision is not aligned with their charity care obligations arising from their favorable tax treatment."

This also raises the question of how many nonprofit hospitals that are failing to meet their charity care obligations continue to be "covered entities" under the 340B program.

340B and Medicaid

Data on charity care and community program spending are reported by hospitals on their IRS Form 990, Schedule H. Another study that examined IRS data confirmed the *JAMA* study's conclusion that Medicaid expansions were associated with lower charity care expenditures. That study concluded that "program (Medicaid) expansion was associated with lower uncompensated care costs and also higher Medicaid payment shortfalls for hospitals. Hospitals in non-expansion states saw only small post-ACA changes in their long-term trends for either uncompensated care or payment shortfalls."[24]

The significant expansion of Medicaid should have caused policy makers to reconsider the 340B program, as many uninsured patients that 340B was intended to help were now insured through Medicaid. The Affordable Care Act significantly expanded Medicaid eligibility, causing enrollment to balloon by 14 million between the summer of 2013 and the beginning of the COVID pandemic in March of 2020.[25] The pandemic caused another spike in Medicaid enrollment, with the Kaiser Family Foundation reporting that between March 2020 and June 2021, Medicaid/CHIP enrollment increased by 12 million.[26] Medicaid enrollment is now 83 million, compared to about 71 million at the beginning of the pandemic. In 2012, prior to the pandemic and the ACA, Medicaid enrollment was 54 million.[27]

Recent trends have indicated a substantial decline in the number of uninsured. As Medicaid expansions were implemented, the number of uninsured declined by 20 million from 2010 to 2016. Between 2017 and 2019, there was a slight uptick in the number of uninsured to 32.8 million non-elderly patients, but this is still below the 35.7 million uninsured in 2014.[28] The bottom line is that the number of uninsured fell from 48.2 million in 2010 to 30 million in 2020.

Given that 340B is intended to help the low-income uninsured population, one would have expected a decline in the size of the 340B program during these significant declines in the number of uninsured. Yet, the opposite happened, between 2010 and 2020, "the number of participating covered entities grew by 50%, from 3,600 unique covered entities to more than 5,000. However, the number of *sites*—provider locations affiliated with these entities—grew seven times over within the same period."[29] These data points are another indication that the 340B program is increasingly unmoored from the population it was intended to help.

Disrupting Community-Based Care

The 340B program has obvious incentives that cause hospitals to acquire physician practices in wealthy communities and designate these practices as "child sites," eligible for 340B discounts. This allows the hospitals to arbitrage those discounts with reimbursements from commercial health plans. Once again, studies have pointed to the expansion of 340B as corrupting the original mission of the program by incentivizing hospitals to expand their suburban presence in order to treat wealthier patients. One study concluded that, "DSH hospitals that registered for the 340B program in 2004 or later served communities with fewer low-income people compared to DSH hospitals that registered before 2004."[30] This study made the obvious point that the acquisition of physician practices in wealthy areas allowed 340B hospitals to "generate profits by prescribing drugs to patients who have private insurance or Medicare."

The 340B program has obvious incentives that cause hospitals to acquire physician practices in wealthy communities and designate these practices as "child sites," eligible for 340B discounts.

The acquisition of community-based physician practices has expanded significantly because of the arbitrage incentives in the 340B program. Certain specialties—oncology gastroenterology, and neurology—are particularly attractive acquisition targets because of the expensive drugs these practices tend to administer. One study found that "approximately 51% percent of oncology practices and 30% of rheumatology, gastroenterology and neurology practices that were independent in 2007 had vertically integrated by 2017."[31]

The growth in the number of hospitals participating in the 340B program has, as one would expect, led to exponential growth in the number of "child sites," many in wealthier areas. "Between 2010 and 2017, the number of enrolled 'parent entities' has increased by over 30 percent. When including 'child sites,' the program grew over the same period by 60% to include 42,029 sites (12,722 parent sites and 29,307 associated sites.)"[32]

This acquisition and consolidation of community-based physician practices has, not surprisingly, led to increased costs. Hospital outpatient care is typically much more expensive than care delivered in a community-based physician-owned practice. As one study put it, "Care in hospital outpatient settings is notoriously more expensive overall. One study funded by the pharmaceutical industry indicated that hospitals markup medicine to five times their acquisition costs for outpatient medicines, and commercial payers reimburse these drugs at rates that are 252 percent of average hospital acquisition costs (without factoring in 340B discounts)."[33]

This acquisition and consolidation of community-based physician practices has, not surprisingly, led to increased costs.

A GAO study found that 340B hospitals tended to prescribe more drugs, and more expensive drugs than other types of hospitals: "GAO found that in both 2008 and 2012, per-beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals. This indicates that, 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."[34] The irony is that a program intended to provide discounted drugs is actually incentivizing hospitals to prescribe more and more expensive drugs.

Consider the Medicare Part B program and how it may drive incentives for 340B hospitals to prescribe more expensive drugs. Medicare Part B reimburses physicians and hospitals for outpatient drugs at 106 percent of Average Sales Price (ASP), a figure determined by actual revenues that manufacturers secure from sales of the drug. Yet, 340B hospitals acquire these drugs at significant discounts but they are reimbursed at the same Medicare rate as non-340B hospitals and physician practices. Therefore, the more expensive the drug, the more potential revenue that is secured by the 340B hospital since the reimbursement by Part B will total 106 percent of ASP.

For example, if the ASP of a drug is $50,000, Medicare will reimburse the hospital at $53,000 for the drug (106 percent of ASP). If the hospital had acquired that drug at a 340B discount of 50 percent, or about $25,000, then the profit for the hospital on that one drug would be approximately $28,000. But consider how a more expensive drug will drive hospital revenue. For a $100,000 drug, the Part B reimbursement will be $106,000. If the hospital acquired the drug at the same 340B discount of 50 percent, then the profit would be $56,000 on that one prescription.

The financial implications for the healthcare system involve more than drug costs. By driving more patients to hospital outpatient settings, the 340B program will drive up the cost of care overall. As one University of Minnesota study put it: "In the end, this policy will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings and unnecessarily prescribed the most expensive drugs so 340B facilities capture the largest profits."[35]

The Troubling Growth of Contract Pharmacies

HRSA issued guidance in 1996 allowing hospitals and other "covered entities" to dispense 340B drugs through an in-house pharmacy or a ***single*** external pharmacy that would contract with the hospital. However, in 2010, HRSA allowed hospitals and other covered entities to contract with an unlimited number of outside pharmacies that could purchase and dispense 340B drugs.[36]

The result was an explosion in the number of pharmacies purchasing and dispensing 340B drugs. One study documented that HRSA's new guidance to allow unlimited contract pharmacies has "led to a 4228% increase in the number of participating pharmacies from 2010 to 2020."[37] One recent study documented that: "In January 2010, fewer than 1,300 unique locations acted as 340B contract pharmacies. As of June 2021, DCI found 29,971 unique locations acting as 340B pharmacies."[38] That same study indicated that for-profit pharmacy chains CVS and Walgreens now have a huge stake in 340B, with 80 percent of all Walgreens stores and two-thirds of CVS stores serving as 340B pharmacies.

One study documented that HRSA's new guidance to allow unlimited contract pharmacies has "led to a 4228% increase in the number of participating pharmacies from 2010 to 2020."

This profitable arrangement for pharmacies was confirmed by a June 2018 GAO audit. "GAO's review of 30 contracts found that all but one contract included provisions for the covered entity to pay the contract pharmacy a flat fee for each eligible prescription. The flat fees generally ranged from $6 to $15 per prescription, but varied by several factors, including the type of drug or the patient's insurance status. Some covered entities agreed to pay pharmacies a percentage of the revenue generated from each prescription."[39] Of course, when pharmacies are paid as a percentage of the revenue from each prescription, they display the same arbitrage incentives of the covered entities, i.e., the more expensive the drug, the wider the spread between the 340B price and the reimbursement price, and the greater the revenue.

This explosive growth in the number of contract pharmacies ushered many for-profit entities into the 340B program. As a USC study documented, "large retail pharmacy chains—Walgreens, CVS, Walmart and Rite Aid—are disproportionately represented among contract pharmacies and together accounted for just over 60% of locations in 2020."[40]

As one would expect, the rush into the 340B program by for-profit firms has likely been driven by one factor: profit-seeking. As one pharmacy expert described the retail pharmacy incentives in the 340B program, "Pharmacies profit from per-prescription fees paid by a 340B qualified entity. These profits are much higher than a pharmacy's typical gross profit from a third-party payer—especially when a 340B covered entity shares a portion of 340B earnings with the pharmacy."[41]

At these contract pharmacies, patients and health plans (both commercial and Medicare) end up providing a significant amount of the profits earned by the pharmacies. As one pharmacy expert put it, "340B prescriptions at contract pharmacies cannot be identified at the time of adjudication."[42] When a patient fills a prescription at one of these pharmacies, the prescription cannot be readily identified as a 340B drug that brings a significant discount. So, the health plan or Medicare Part D will reimburse the drug at the full price, not knowing that the pharmacy and hospitals purchased the drug at, for example, a discount of 75 percent or more. Moreover, the patient's copay or coinsurance will not be lowered because the drug was purchased at a 340B discount; the patient's out-of-pocket costs will be based upon the faulty assumption that the prescription is being filled at the standard, not the discounted, price.

Retail pharmacies are not the only for-profit entities benefitting from the 340B program. The $472 billion for-profit pharmacy benefit management (PBM) industry, led by Cigna, CVS Health and UnitedHealthcare, is also reaping significant profits from the 340B program.[43] These profits derive from the fact that PBMs own a significant portion of the nation's "specialty pharmacies"—those that infuse or inject drugs that are many times more expensive than the pills a patient picks up in a yellow bottle at the pharmacy.

As with retail pharmacies, hospitals write contracts with specialty pharmacies that offer lucrative fees and allow the specialty pharmacy to share in a percentage of the revenue secured by the hospitals' arbitrage of the 340B discount. As one pharmacy expert notes, under these contracts, "the contract pharmacy earns profits that are three to four times larger than a specialty pharmacy's typical gross profit from a third-party payer."[44]

PBMs have also found that their large mail order business can benefit significantly from 340B discounts. Mail order purchases of non-340B drugs have shown healthy average growth rates of about 9 percent; mail order purchases of drugs eligible for 340B discounts grew at an annual rate of 56 percent between 2017 and 2020.[45]

While it is troubling that huge for-profit companies are securing billions in profits from a program intended to help low-income and uninsured patients, perhaps more troubling is that the 340B contract pharmacy world is rife with violations of federal law. This law-breaking comes in the form of "duplicate discounts."

The law creating the 340B program explicitly banned 340B entities from billing drug manufacturers for multiple discounts. For example, a Medicaid patient treated at a 340B hospital goes to the pharmacy to fill her prescription. The pharmacy is a 340B pharmacy and the drug has been bought by the hospital at a 50 percent discount under the 340B program. For simplicity's sake, let's say the hospital has paid $50 for the drug that, to other customers, costs $100. At the pharmacy counter, the patient presents the pharmacist with her Medicaid managed care drug card. The patient's prescription comes with a manufacturer's rebate of 60 percent, a percentage not uncommon for Medicaid drugs.

Under the duplicate discount problem, the hospital has paid the drug manufacturer $50 for the drug, but the manufacturer receives an invoice to pay Medicaid a $60 rebate under the federal rebate law. This hypothetical prescription has cost the drug manufacturer $10, i.e., the manufacturer loses money every time its prescription for their drug is filled.

This type of arrangement is illegal under the 340B statute but, despite this fact, hospitals, contract pharmacies and others benefitting from this arrangement have not fixed the problem, even after multiple reports by federal watchdogs, including the GAO and the USHHS Inspector General.[46, 47, 48] While the OIG and GAO have highlighted the duplicate discount problem for more than a decade, their recommendations have gone unheeded. Here is the GAO recommendation from 2018 that has yet to be acted upon: "The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs."[49]

Federal Policy Recommendations

The 340B program is obviously in need of significant reform. A program intended to help low-income patients and the uninsured has become a cash cow for those administering the program, including multibillion dollar for-profit companies.

1. *Require hospitals to report revenues from 340B programs*

Along with more reliable reporting of charity care expenditures, hospitals and other covered entities should be required to report ***all*** revenues generated through the 340B program. Contract pharmacies participating in the program should have similar transparency obligations. Advocates for the 340B program issue many press releases and reports citing anecdotal examples of charity programs that assist vulnerable populations. These press releases and reports do not reliably report the *amount* of revenue secured each year from the 340B program and how much of that revenue finds its way to charity care discounts and programs. As this report has documented, 340B revenue has exploded in recent years and policy makers should have reliable assurances that this revenue is being deployed to assist vulnerable populations. In short, there should be full transparency regarding the amount of revenue flowing into covered entities from the 340B program and how, specifically, all that revenue is being spent.

Along with more reliable reporting of charity care expenditures, hospitals and other covered entities should be required to report all revenues generated through the 340B program.

2. *Require covered entities to spend all revenues from 340B programs on charity care and community programs*

In addition to simple transparency, covered entities should be required to spend ***all*** revenues generated through 340B programs on two things: drug discounts for vulnerable populations and charity care programs for those same populations. Congress should specifically define "vulnerable populations" in statute so 340B revenues cannot be used to replace uncollected debts from wealthy patients or to subsidize other non-charity care obligations.

3. *Define patients eligible for drug discounts and charity care programs*

There is considerable evidence that many hospitals have adopted conscious strategies to open "child sites" in upper income areas to arbitrage 340B discounts. This strategy runs counter to the original goals of the authors of the 340B statute. The program was not intended to help the wealthy access discounted drugs to drive hospital revenue. Congress should, by statute, precisely define the income categories of patients who are eligible for discounted 340B drugs and for charity care assistance. For example, patients enrolled in the Low-Income Subsidy (LIS) program in Medicare Part D should be automatically eligible for charity care programs and assistance as should patients enrolled in the Qualifying Individuals (QI) Program in Part B. Middle- and upper-income patients should not be eligible for discounted drugs or charity care programs and programs that serve middle- and upper-income populations should not be counted as charity care.

4. *Disqualify child sites in wealthy areas from the 340B program*

Given the obvious strategy of many hospitals to locate child sites in wealthy areas to bring 340B discounts to upper income patients, Congress should render child sites ineligible for 340B if the neighborhoods where they are located do not meet certain federal thresholds for impoverished areas. Congress should study the recent growth of child sites to determine if they are being located in areas with median incomes above 120 percent of the poverty level. If these sites are being located in higher income areas, Congress should consider legislative solutions to refocus the placement of child sites.

5. *Standardize the definition of charity care and community programs*

Congress should promulgate, by statute, a strict and reliable definition of "charity care." 340B entities are required to report their charity care amounts on various federal filings such as IRS 990 forms and Medicare (CMS) Cost reports. The problem is that the figures that land in those filings are quite opaque. For example, if a commercially insured patient fails to pay the coinsurance payment for an infused drug, can a hospital write off that debt as "charity care?" It appears that some hospitals may count this as charity care, while others do not. A standard definition and stricter reporting requirements are sorely needed so policy makers can have some assurance that the vast, and rising, revenues from the 340B program are benefitting needy populations.

Congress should promulgate, by statute, a strict and reliable definition of "charity care."

6. *Reform disproportionate share hospital eligibility requirements for 340B programs*

When the Affordable Care Act (ACA) was passed, Medicaid eligibility underwent a significant expansion (as described above). Since institutions acquire 340B eligibility based upon their level of care for Medicaid patients, thousands of new covered entities were created by the ACA.[50] This Medicaid threshold seems an inexact method for establishing 340B eligibility. Medicaid patients are, after all, insured patients. We would recommend that Congress establish different eligibility requirements for 340B participation that are more closely related to the level of care provided to the uninsured and truly low-income populations.

7. *Convert 340B discounts to rebates*

As described above, duplicate discounts are not only a violation of federal law, but quite common in the 340B program. One pharmacy software provider found $100 million in duplicate discounts in just a sample of claims that they analyzed.[51] They believe the number of duplicate discounts runs much higher than $100 million. They propose a simple solution to this problem: rather than offering 340B drugs through a discount program, provide rebates after adjudication to secure the 340B price. This software company points out that the AIDS Drug Assistance Program (ADAP) receives its 340B discounts in the form of a rebate and therefore they are able to ascertain when a duplicate discount may occur. Fraud is a significant problem in federal healthcare programs and when federal law is flouted—as it blatantly is with duplicate discounts—it sends the message that the federal government is not serious about enforcing laws it enacts.

PART II: Trends in Charity Care in a Sample of Massachusetts' Hospitals

According to data from the program's administrator, the Health Resources and Services Administration (HRSA), purchases of discounted 340B drugs have more than quadrupled in value since 2014.[52] The pharmacy blog *Drug Channels* submitted a FOIA request to HRSA indicating: "The compound average growth rate for the program was 27% from 2014 through 2020." Drug purchases under the program reached at least $38 billion in 2020, and the program now exceeds the size of the Medicaid program's outpatient drug sales. According to the authoritative consulting firm IQVIA, the non-discounted value of the drugs running through the 340B program was $80.1 billion in 2020, with for-profit contract pharmacies responsible for 30 percent of the program.

Given the explosive growth in 340B revenues flowing into "covered entities," such as hospitals, between 2014 and 2020, we wanted to examine the trends in charity care for a sample of Massachusetts hospitals. The sample was chosen based exclusively upon geography, not size or level of charity care. However, two hospital groups, Boston Medical Center, and the Cambridge Health Alliance (which consists of Cambridge Hospital and Everett Hospital) were included in the sample because they consistently provide the highest level of charity care in the state, and we wanted to examine their trends from 2013–2020.

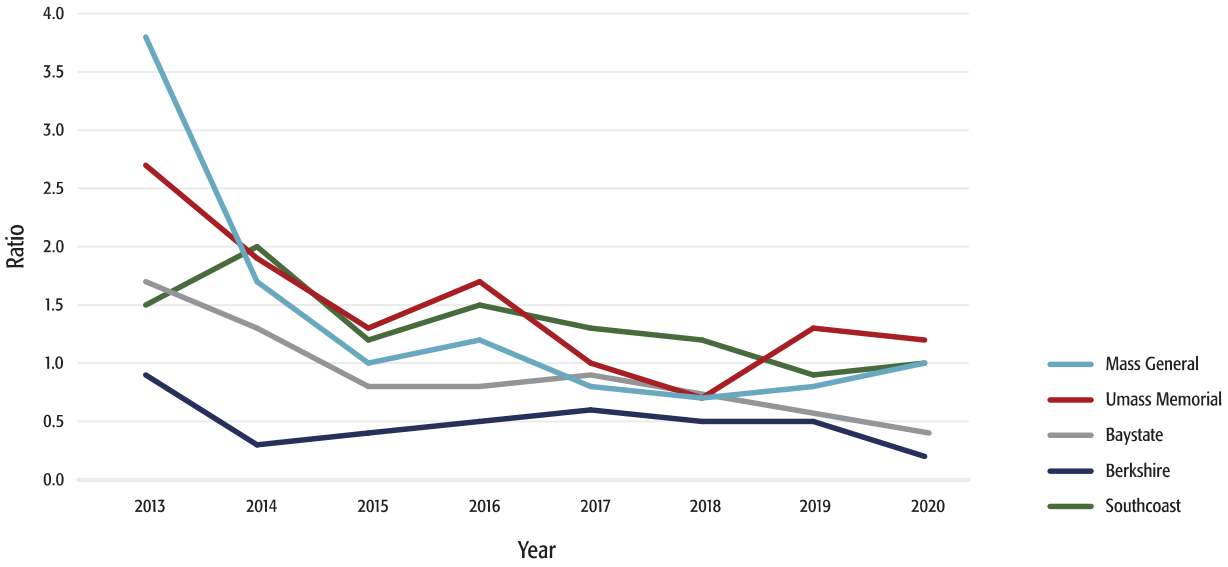
The level of charity care was taken from Medicare Hospital Cost Report Worksheet S-10, column 3, line 23 for each institution, which includes charity care for both the uninsured or patients with coverage from an entity that does not have a contract with the provider and insured patients on commercial insurance or a public program with a contract with the provider. As explained in other research, the charity care, "for uninsured patients is measured as the cost of the services (the charges for the services multiplied by the hospital's cost-to-charge ratio) offset by any partial payments. Charity care for insured patients consists of the amount owed for deductible and coinsurance payments written off by the hospital according to the hospital's charity care policy without expectation of payment, offset by any partial payments, after certain adjustments. This cost-based measurement of charity care mitigates the risk that hospitals with high charges report inflated charge-based charity care."[53]

In our sample of hospitals, there was an unmistakable trend: charity care has been declining significantly since 2013 in a number of important hospitals across the state.

There are many methods that could be used to compare charity care levels between institutions of different sizes; this paper calculates charity care amounts relative to revenue in an effort to allow for a more apples-to-apples comparison. We acknowledge that there may be some limits to this method, but felt that looking at the same comparison over time provides an important picture of the changes happening with charity care levels.

In our sample of hospitals, there was an unmistakable trend: charity care has been declining significantly since 2013 in a number of important hospitals across the state. Massachusetts General Hospital, the largest hospital in Massachusetts with over 23,000 employees, saw a decline in spending on charity care from 3.8 percent of patient revenues in 2013 to just 1 percent of patient revenues in 2020. In every hospital in our survey, the high-water mark for the provision of charity care to the community peaked in either 2013 or 2014. Five regional hospitals saw declines of 50 percent or more.

Selection of Massachusetts Hospitals Total Charity Care/Net Patient Revenue 2013–2020



Some of these declines could be due to Medicaid expansions enacted as part of the Affordable Care Act. That law expanded Medicaid eligibility to new segments of the population and raised the income threshold for Medicaid eligibility. On the federal level, that expansion took effect on January 1, 2014. However, states could also "opt-in" to the more generous expansions of Medicaid eligibility, which Massachusetts chose to do when Governor Deval Patrick signed legislation in August of 2013. States choosing to expand their Medicaid programs received more generous federal matching funds.[54]

These figures raise a significant policy issue for the 340B program. Purchases through 340B rose from $9 billion in 2014 to $38 billion in 2020. It seems beyond doubt that Massachusetts hospitals would have secured a significant increase in revenue during this expansion of the 340B program. Why, then, did we not see a significant rise in the provision of charity care during this period? One can point to the expansion of Medicaid as a factor, as more patients would have entered the hospital with insurance. Yet, if there was a declining need for charity care, why did the 340B program expand so exponentially? Shouldn't the program have witnessed a decline when the populations it was intended to serve gained insurance coverage?

For the two hospitals chosen in our survey based upon their generous rates of charity care, the declines were not as pronounced and seem not to have been directly related to Medicaid expansion. For example, the Cambridge Health Alliance's high-water mark for charity care was in 2014, when 15.4 percent of patient revenue was devoted to charity care. However, their charity care numbers declined to 6 percent of patient revenues in 2017–18 but spiked to 10.6 percent of patient revenues by 2019. Likewise for Boston Medical Center, the Medicaid expansion seems not to have had a direct impact upon their provision of charity care as their spending rose from 10.8 percent in 2013 to 14 percent in 2016 before declining to 7.4 percent in 2020.

Boston Medical Center and Cambridge Health Alliance Hospitals Total Charity Care/Net Patient Revenue 2013–2020

While hospitals are not required to report revenues deriving from the sale of 340B drugs, it seems very likely that 340B sales to the five Massachusetts hospitals were growing. We can make this supposition based upon the number of contract pharmacy relationships that developed in roughly the years when charity care was declining.

According to the Health Resources and Services Administration's Office of Pharmacy Affairs, here is the growth in contract pharmacy relationships in the last decade:

- UMass Memorial: 2012 - 3 contract pharmacies, 2022 - 196 contract pharmacies
- Baystate Medical Center: 2012 - 79 contract pharmacies, 2022 - 169 contract pharmacies
- Mass General Hospital: 2017 - 1 contract pharmacy, 2022 - 132 contract pharmacies
- Berkshire Medical Center: 2013 - 2 contract pharmacies, 2022 - 71 contract pharmacies
- Southcoast Hospitals: 2015 - 24 contract pharmacies, 2022 - 66 contract pharmacies

State Policy Recommendations

While states cannot change many elements of how 340B is administered, they can bring greater transparency to the program in their state and offset bad behavior when it is identified.

1. *Set a standard definition of charity care and 340B reporting, require annual reporting, and audit some reports submitted*

Instead of waiting on the federal government to define "charity care," states can set an example that federal officials can follow by establishing strict and reliable definitions. Those definitions should focus on the cost of care provided for the uninsured or to services for individuals under a certain income level.[55] It should not allow for loopholes that exist now of writing off "under reimbursement" by public programs when compared to the chargemaster rate, which is meaningless. Prompt pay or community education or outreach, which often looks more like marketing, should not be allowed either. Once this standard is set, hospitals shall, or the state should, reserve the right to have any report audited to prevent gaming of the reporting. At minimum, states should require annual reporting on the amount of charity care being offered by a hospital broken down by the different categories of charity care as laid out in the hospital's charity care policy. This change in definition may require changing the definition of community benefit to charity care in state law, or if it is not defined in state law, attorneys general or state agencies

have regulatory authority as part of the licensing, consumer protection, and non-profit registration process to set such definitions.

2. *Require hospitals to report on their revenue from 340B each year to see trends emerge and better inform state and federal policy.*

State agencies or legislative committees could then use these reports to better understand outlier institutions, and discuss possible future policy actions or recommendations to remedy potential abuse or misuse of the program.

Conclusion

There are innumerable federal programs that were conceived with the best of intentions. In urban and rural areas, and even in suburbs, there are many Americans in need of social welfare assistance: food, healthcare, clothing, housing, and drug treatment and mental health services. The list of needs is lengthy.

There is, unfortunately, an unflattering pattern for some federal programs that were designed to provide these social welfare needs. Programs that were begun to serve genuinely needy populations can become captives of the vendors who provide the services. As in the national security realm, there is a social welfare industrial complex of companies and organizations that benefit handily from these federal programs regardless of whether services are being delivered more efficiently or effectively to the needy.

This dubious pattern for federal programs is on full display with 340B. A program that was intended to serve the needs of the low-income uninsured is now a fountain of revenue for hospitals, clinics, for-profit pharmacies and pharmacy benefit managers while, the data strongly suggest, these same entities have pulled back from providing charity care, drug discounts, and community programs. Expanding the 340B program has certainly been a lucrative source of revenue for covered entities, but it has also served to enrich for-profit pharmacy chains and pharmacy benefit management firms, weakened community-based physician and oncology care, pushed patients into more expensive hospital-based care, created incentives for more expensive therapies—all while providing fewer and fewer services to the low-income uninsured. All these trends occurred while executives at nonprofit hospitals secured record compensation.[56]

The 340B program cries out for reform. The road to reform will be challenging, as so many actors are now securing financial benefits from the program. Reform, nonetheless, is urgently needed.

Endnotes

1 https://www.hrsa.gov/opa/index.html

2 https://communityoncology.org/the-340b-program-in-review-a-look-at-the-data-and-evidence-to-date/

3 https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html

4 https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf

5 https://340breform.org/wp-content/uploads/2021/05/AIR340B-Neal-Masia-Report.pdf

6 https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0540

7 https://www.gao.gov/assets/gao-21-107.pdf

8 https://www.340bhealth.org/newsroom/report-340b-hospitals-are-directing-savings-toward-their-communities-unique-needs/

9 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078

10 https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html

11 https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html

12 https://www.340bhealth.org/files/MA.pdf

13 https://www.nejm.org/doi/full/10.1056/nejmsa1706475

14 https://340breform.org/wp-content/uploads/2021/04/AIR340_LeftBehind-v6.pdf

15 H.R. Rep. 102-384, Pt. 2 (1992).

16 https://www.irs.gov/charities-non-profits/charitable-organizations/requirements-for-501c3-hospitals-under-the-affordable-care-act-section-501r

17 https://www.modernhealthcare.com/article/20180106/NEWS/180109941/charity-care-spending-flat-among-top-hospitals

18 https://healthpolicy.usc.edu/wp-content/uploads/2021/10/USC_Schaeffer_340BDrugPricingProgram_WhitePaper.pdf

19 https://healthpolicy.usc.edu/wp-content/uploads/2021/10/USC_Schaeffer_340BDrugPricingProgram_WhitePaper.pdf

20 https://pubmed.ncbi.nlm.nih.gov/32187392/

21 https://www.modernhealthcare.com/article/20180106/NEWS/180109941/charity-care-spending-flat-among-top-hospitals

22 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2760774

23 https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01627

24 https://academyhealth.confex.com/academyhealth/2017arm/meetingapp.cgi/Paper/16795

25 https://www.macpac.gov/subtopic/medicaid-enrollment-changes-following-the-aca/

26 https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/

27 https://www.kff.org/medicaid/issue-brief/medicaid-enrollment-june-2012-data-snapshot/

28 https://aspe.hhs.gov/sites/default/files/private/pdf/265041/trends-in-the-us-uninsured.pdf

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

30 https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0540

31 http://infusioncenter.org/wp-content/uploads/2020/11/Concerns-Surrounding-the-340B-Program-Kindyl-Boyer.pdf

32 https://jupiterls.com/wp-content/uploads/2020/08/340b-in-2020-JLSC-white-paper-July-2020.pdf

33 https://www.themorancompany.com/wp-content/uploads/2018/09/Hospital-Charges-Reimbursement-for-Medicines-August-2018.pdf

34 GAO found that in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals. This indicates that, 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.

35 https://carlsonschool.umn.edu/sites/carlsonschool.umn.edu/files/inline-files/340BMinnesotaWhitePaper%20%281%29.pdf

36 HRSA did not green light this expansion in the number of contract pharmacies through rulemaking that followed the federal Administrative Procedure Act (APA). HRSA simply issues "sub regulatory" guidance that may not even be legal.

37 https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/

38 https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html

39 https://www.gao.gov/products/gao-18-480

40 https://healthpolicy.usc.edu/wp-content/uploads/2021/10/USC_Schaeffer_340BDrugPricingProgram_WhitePaper.pdf

41 https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html

42 https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html

43 https://www.ibisworld.com/industry-statistics/market-size/pharmacy-benefit-management-united-states/

44 https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html

45 https://www.drugchannels.net/2021/07/specialty-pharmacys-explosive-340b.html

46 https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf

47 https://oig.hhs.gov/oei/reports/oei-05-14-00430.asp

48 https://www.gao.gov/assets/gao-11-836.pdf

49 https://www.gao.gov/products/gao-18-480

50 https://www.politico.com/interactives/2017/obamacare-non-profit-hospital-taxes/

51 https://www.drugchannels.net/2020/08/improve-compliance-and-create.html

52 https://www.drugchannels.net/2021/09/exclusive-340b-program-soared-to-38.html

53 https://www.healthaffairs.org/do/10.1377/forefront.20210903.507376/full/

54 https://www.advisory.com/en/daily-briefing/2012/11/09/medicaidmap

55 It should be noted that allowing a hospital to state their cost to provide a service still bakes in inefficiencies and cross subsidization that have been shown to exist in many large hospital settings.

56 https://www.forbes.com/sites/adamandrzejewski/2019/06/26/top-u-s-non-profit-hospitals-ceos-are-racking-up-huge-profits/?sh=3249a19619df

About the Authors

William Smith is Senior Fellow in Life Sciences at Pioneer Institute. He has 25 years of experience in government and in corporate roles, including as vice president of public affairs and policy at Pfizer, and as a consultant to major pharmaceutical, biotechnology and medical device companies. He held senior staff positions for the Republican House leadership on Capitol Hill, the White House, and in the Massachusetts Governor's office. He is affiliated as research fellow and managing director with the Center for the Study of Statesmanship at The Catholic University of America (CUA), where he earned his PhD.

Josh Archambault is President and Founder of Presidents Lane Consulting. He is a Senior Fellow at both the Cicero Institute and Pioneer Institute. His work experience has ranged from work as a Senior Legislative Aide to a governor, Legislative Director for a state senator, to years working for think tanks operating in thirty-five states, and in D.C. He is a regular contributor to the influential Forbes.com blog, The Apothecary. Josh holds a master's in public policy from Harvard University's Kennedy School of Government and a B.A. in political studies and economics from Gordon College.

Mission

Pioneer Institute develops and communicates dynamic ideas that advance prosperity and a vibrant civic life in Massachusetts and beyond.

Vision

Success for Pioneer is when the citizens of our state and nation prosper and our society thrives because we enjoy world-class options in education, healthcare, transportation and economic opportunity, and when our government is limited, accountable and transparent.

Values

Pioneer believes that America is at its best when our citizenry is well-educated, committed to liberty, personal responsibility, and free enterprise, and both willing and able to test their beliefs based on facts and the free exchange of ideas.

PIONEER INSTITUTE
PUBLIC POLICY RESEARCH

185 Devonshire Street, Suite 1101 Boston MA 02110 617.723.2277
www.pioneerinstitute.org Facebook.com/PioneerInstitute Twitter.com/PioneerBoston

Connecticut Office of the Attorney General

340B Litigation Update

Report to DSS 340B Working Group

December 19, 2023

Takeaways from the OAG's 340B Actions

- 340B has received broad, bipartisan support since its creation by Congress in 1992. It is a lifeline for low-income patients and community-based providers. Preserving access to affordable medication, including through use of "contract" pharmacies, is critical.

- Program has evolved and expanded significantly since its inception. Regulations, enforcement, and audit authority at the federal Health Resources and Services Administration (HRSA) must keep pace.

- Drug manufacturers should not unilaterally impose their own conditions on covered entities because they are unhappy with the pace of reform.

- Can states step in? Drug manufacturers actively challenging state efforts to regulate in this space on preemption grounds.

Office of the Attorney General
340B Actions to Date

- **October 6, 2020:** Attorney General Tong sends letters to drug makers Eli Lilly, Astra Zeneca, Merck, Sanofi, and Novartis calling on companies to honor contract pharmacy orders. Letter takes issue with the companies imposing unilateral changes to participation in the program, instituting new data sharing requirements that may violate federal health privacy laws, and abruptly refusing to ship drugs to contract pharmacies.

- **December 14, 2020**: Attorney General Tong leads bipartisan multistate coalition urging U.S. Department of Health and Human Services (HHS) to hold accountable drug manufacturers who are unlawfully and unilaterally refusing to provide discounts and/or ship to contract pharmacies.

- **December 31, 2020**: Attorney General Tong praises HHS advisory opinion concluding that drug manufacturers are required to deliver 340B discounts to contract pharmacies.

- **May 16, 2022:** Attorney General Tong leads bipartisan multistate coalition filing two amicus briefs defending actions in the D.C. Circuit and 3rd Circuit Court of Appeals against drug manufacturers refusing to comply with contract pharmacy orders.

- **July 28, 2023**: Attorney General Tong leads bipartisan multistate letter in response to Senate request for information seeking to improve integrity and sustainability of 340B program.

340B Litigation Streams

- Contract pharmacy litigation
- Federal preemption litigation
- Patient definition litigation

Contract Pharmacy Litigation

- Series of cases brought by drug manufacturers across multiple federal district courts against HRSA/HHS for issuance of violation letters
- Ultimate legal question in all cases:
  - **Does 42 U.S.C.S. § 256b require drug makers to deliver drugs to an unlimited number of contract pharmacies?**
- Three circuit court cases:
  - *Sanofi Aventis LLC v. United States HHS*, 58 F 4th 696 (3rd Circuit 2023) – held that drug makers are not required to deliver drugs to an unlimited number of contract pharmacies.
  - *Eli Lilly and Company et al. v. Becerra/U.S. Department of Health and Human Services et al.* (7th Circuit) (Awaiting Decision)
  - *United Therapeutics Corporation v. Carole Johnson, et al.*; *United Therapeutics Corporation v. Espinosa et. al.* (D.C. Circuit) (Awaiting Decision)

Federal Preemption Litigation

- *PhRMA v. McClain et al. (Arkansas)* – 8th Circuit
  - Arkansas Act 1103 provides that manufacturers (1) may not prohibit pharmacies from contracting with 340B covered entities by denying access to the drugs they make and (2) may not deny 340B pricing "for an Arkansas-based community pharmacy" that receives 340B-purchased drugs under a 340B contract pharmacy arrangement.
  - The Arkansas Insurance Department further published implementing regulations in September 2022.
  - Arkansas federal district judge ruled in December 2022 that Arkansas Act 1103 is not preempted by the 340B statute nor the Food, Drug, and Cosmetic Act (FDCA).
- PhRMA appealed to the 8th Circuit – Oral arguments held; awaiting final decision

Federal Preemption Litigation

- *PhRMA v. Landry (Louisiana)* – W.D. Louisiana
  - In July 2023, PhRMA preemptively filed suit in the U.S. District Court for the Western District of Louisiana challenging provisions in Louisiana Act 358 that seek to require manufacturers to provide 340B-priced medicines to pharmacies under contract with a 340B covered entity.
  - AstraZeneca and AbbVie filed a similar suits in the U.S. District Court for the Western District of Louisiana alleging that Louisiana Act 358 is unconstitutional and an "erroneous interpretation of federal law." The manufacturers allege that Act 358 violates both the Supremacy Clause and the Contracts Clause of the U.S. Constitution.
  - All three cases (*PhRMA, AstraZeneca,* and *AbbVie*) are currently briefing motions to dismiss and oppositions

Patient Definition Litigation

- *Genesis Health Care, Inc. v. Becerra* – U.S. District Court for District of South Carolina
- Litigation dealing with definition of "patient" for purposes of the 340B program
- Litigation arises from a HRSA audit of Genesis Healthcare, a South Carolina-based FQHC
  - HRSA alleged that Genesis dispensed 340B drugs to ineligible patients and moved to remove Genesis from 340B program
  - HRSA eventually allowed Genesis back into 340B program, Genesis moved the court to block HRSA from enforcing a stricter definition of "patient" than what is included in the 340B statute
- Court ruled that the HRSA's restrictive interpretation of the term "patient: was contrary to the plain language of the 340B Statute, and the statute instead supported a "broad reading" of the term

State Transparency Requirements

- Minnesota and Maine both recently passed transparency laws requiring 340B covered entities to report:
  - Minnesota (all covered entities)
    - Aggregated acquisition cost of 340B drugs
    - Aggregated payment received for 340B drugs
    - Aggregated payments made to contract pharmacies for dispensing
  - Maine (hospitals only)
    - Uses of 340B program savings
    - Data comparing 340B acquisition price to group purchasing organization acquisition price
- Both laws have not yet been challenged by PhRMA and/or covered entities

MEMORANDUM

TO: Mehul Dalal, Chief Policy Advisor, CT Department of Social Services
Joel Norwood, Deputy Chief Policy Advisory, CT Department of Social Services

FROM: Paul Kidwell, Senior Vice President, Policy, Connecticut Hospital Association

DATE: December 15, 2023

SUBJECT: 340B Program – Hospital Covered Entity Perspective

340B General Purpose

The 340B program was established over 30 years ago to allow hospitals and other covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The program sets eligibility criteria so that only certain hospitals may enroll in 340B. Once enrolled, hospitals access drug discounts which provide the financial resources that assist each hospital in meeting the specific needs of patients in vulnerable communities. In many instances, this assistance allows hospitals to provide services that would otherwise be unavailable. Without 340B, many patients would need to seek care elsewhere or may go without care completely.

The assistance made possible by the 340B program is felt by communities across the state, but is especially important to some of Connecticut's largest urban centers like Bridgeport, Hartford, New Haven, Stamford, and Waterbury. The health inequity across the United States, laid bare by the uneven impact COVID-19 has had on our communities, reinforces the ongoing need for the investments 340B savings allow.

340B Program Patient and Community Benefit

The savings derived from 340B — meaning the difference between the discounted 340B price and the non-discounted price hospitals would otherwise be required to pay — supports the nearly $1 billion in unreimbursed care for low-income Medicaid beneficiaries provided each year, the nearly $250 million in uncompensated care (charity care/bad debt) provided each year, and the millions in community investments provided each year by hospitals across the state.[1]

The purpose of the 340B program is for covered entities to use the program broadly to reach more eligible patients and offer more comprehensive services. Hospitals are able to support their critical financial assistance policies, which provide free and reduced cost care, in part due to 340B program savings. Connecticut hospitals strive to ensure that inability to pay for services does not deter anyone from seeking needed medical care, and 340B program participation helps support the ability of hospitals to offer financial assistance policies beyond the

[1] 2023 Community Benefit Report, Connecticut Hospital Association, https://www.cthosp.org/documents/web/CHA%20website/2023%20toolkit/FINALCBRprint.pdf.

state's statutory financial assistance requirements, helping to ensure more patients are able to afford their medical care.

340B Savings Supports Patient Care and Community Investment During Difficult Financial Times for Hospitals

According to the Annual Report on the Financial Status of Connecticut's Short Term Acute Care Hospitals[2] released by the Office of Health Strategy (OHS), hospitals across Connecticut are facing significant economic headwinds that threaten their financial health and sustainability. The OHS report echoes findings of a study completed and released this year by the health economics firm, Kaufman Hall.[3] Hospital expenses have climbed by $3.3 billion since before the pandemic, OHS reports, and revenues are not keeping pace, leading to a negative statewide hospital operating margin of -1.3% in Fiscal Year 2022. The OHS report details how the rising costs of drugs, contract labor, and salaries and wages for medical personnel are driving the growth in expenses, at the same time hospitals are spending more on uncompensated care including insufficient Medicaid and Medicare reimbursements.

In addition to facing rapidly rising costs and negative operating margins, hospitals are spending more to provide uncompensated care for patients, according to OHS, with the expense of providing charity care (free care) and bad debt (unpaid costs) rising 9.6% in one year. While expenses have risen dramatically, payments for care remain insufficient. The OHS report indicates that Medicare reimbursements in the state averaged only 74 cents on the dollar, and Medicaid reimbursed only 62 cents on the dollar in FY 2022.

The 340B Program has blunted what would be even more serious financial challenges without the savings derived by hospitals from the program. In periods of severe financial strain, 340B savings are even more important than ever, preserving support for community investments, clinical programs, and patient financial assistance.

Existing Hospital Financial and Community Benefit Reporting Offers Significant Information and Transparency

Existing hospital reporting requirements provide significant transparency documenting that 340B hospitals use 340B savings to help serve their disproportionate share of low-income patients.

- **Medicare cost report Form S-10**. All hospitals participating in the Medicare program are required to file a Medicare cost report. This detailed report on hospital finances, volume, and facilities includes Form S-10, which provides hospital-level data on the dollar amount of financial assistance provided, bad debt, and shortfalls from means-tested government programs.[4]
- **IRS Form 990 Schedule H**. The IRS requires tax-exempt hospital organizations to report extensively on the net costs of community benefit activities on Schedule H of Form 990. This schedule covers the net cost of providing financial assistance, subsidizing various services, bad debt attributable to people who would likely qualify for financial assistance, shortfalls from means-tested government programs, and other community benefits. It requires the organization to provide the number of patients served for each community benefit activity and the percentage that the net costs associated with these activities represent of total expenses. Hospital organizations also report community-building activities, including physical improvements and housing, economic development, community support (childcare, support groups, violence prevention), environmental improvements, leadership development, coalition building,

[2] Financial Status of Connecticut's Short Term Acute Care Hospitals, Office of Health Strategy, https://portal.ct.gov/-/media/OHS/HSP/OHS_Financial-Stability-Report_FY-2022.pdf.
[3] The Financial Impact of the COVID-19 Pandemic on Connecticut Hospitals, Kaufman Hall, https://www.cthosp.org/documents/pubreports/2023/Kaufman.Hall.CT.Hospitals.Financial.Health%20-%20FINAL%203.2.23.pdf.
[4] Centers for Medicare and Medicaid Services. Form CMS-2552-10, Worksheet S-10 – Hospital Uncompensated and Indigent Care Data. https://www.costreportdata.com/instructions/Instr_S100.pdf.

community health improvement advocacy, workforce development, and others. Hospitals must disclose their funding sources for these activities.

- **Community health needs assessment (CHNA).** Each nonprofit hospital is required to conduct and make available to the public a CHNA every three years. A CHNA is an assessment of the significant health needs of the community and must take into account input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health, and must be made widely available to the public. The hospital must develop and make public an implementation strategy to meet the community health needs identified through the CHNA. In 2022, Connecticut revised and expanded its community benefit reporting statute providing more detailed and annual information about the significant contributions Connecticut hospitals make to their communities.

Drug Company Restrictions on the Appropriate Operation of the 340B Program

Over the last few years, more than two dozen drug manufacturers have restricted access to 340B pricing for drugs dispensed by contract pharmacies. Manufacturer restrictions, which were found to be unlawful by the Department of Health and Humans Services, are now being litigated in federal court and are being challenged in states like Arkansas. These restrictions, which often limit the number of contract pharmacies a covered entity may use or limit the maximum distance between a hospital and a contract pharmacy, are restricting the value of the program to countless low-income patients and harming the underlying purposes of the 340B Program.

According to 340B Health, a national, not-for-profit organization founded to advocate on behalf of 340B hospitals, the 21 drug manufacturers imposing contract pharmacy restrictions as of June 2023 account for $8.4 billion in program savings nationally.[5] These restrictions are putting billions of dollars at risk which should be used to benefit patients and fund 340B-supported programs and services offered by 340B covered entities.

PK:ljs
cc: Members, 340B Work Group

[5] Drugmakers Pulling $8 Billion Out Of Safety-Net Hospitals, 340B Health, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.

Norwood, Joel C.

From: Kidwell, Paul <Kidwell@chime.org>
Sent: Friday, December 22, 2023 11:07 AM
To: Dalal, Mehul; Norwood, Joel C.
Subject: 340B Work Group -- Additional Submission

Follow Up Flag: Follow up
Flag Status: Flagged

Good morning,

In addition to the memorandum I sent you last week, I also would like to share a document prepared by Healthsperien and funded by the American Hospital Association. It provides a comprehensive view of the 340B program. Additionally, I wanted to make sure the record reflected the history of why the program was authorized in the first place.

In 1990, Congress created the Medicaid Drug Rebate Program. As you know, it requires pharmaceutical manufacturers to provide rebates for outpatient drug purchases, based on sales to Medicaid beneficiaries, as a condition of having their products covered by Medicaid. The amount of the rebates paid to the states were based on a "best price" calculation that did not take into account the discounted prices that manufacturers were offering directly to federally funded clinics and public hospitals serving large numbers of low-income and uninsured patients.

In 1992, Congressional hearings found that failing to exempt these voluntary discounts under the Medicaid Drug Rebate Program caused prices to rise for the facilities referenced above. The steep rise reflected the size of the discounts previously offered, and the shift once "best prices" were imposed in place of voluntary discounts. Consequently, Congress created the 340B program in November 1992 which protected specified clinics and hospitals ("covered entities") from drug price increases and gave them access to price reductions.

As you draft the report, I wanted to make sure you were aware of some of this past history and why the program was established.

Thank you,
Paul

CHA CONNECTICUT HOSPITAL ASSOCIATION

Paul Kidwell
Senior Vice President, Policy
Phone 203.294.7247
E-mail kidwell@chime.org
110 Barnes Rd., Wallingford CT 06492

CARING FOR CONNECTICUT

Norwood, Joel C.

From: Kidwell, Paul <Kidwell@chime.org>
Sent: Monday, January 15, 2024 10:22 PM
To: Dalal, Mehul
Cc: Norwood, Joel C.
Subject: Re: 340B Work Group -- Additional Submission

Thanks, Mehul. Wanted to note that some of this information is sourced through Wikipedia as it provides a well sourced and comprehensive look at the program. Noticed that I failed to note that in my earlier correspondence.

On Dec 27, 2023, at 9:58 AM, Dalal, Mehul <Mehul.Dalal@ct.gov> wrote:

Received, thank you

From: Kidwell, Paul <Kidwell@chime.org>
Sent: Friday, December 22, 2023 11:07 AM
To: Dalal, Mehul <Mehul.Dalal@ct.gov>; Norwood, Joel C. <Joel.Norwood@ct.gov>
Subject: 340B Work Group -- Additional Submission

Good morning,

In addition to the memorandum I sent you last week, I also would like to share a document prepared by Healthsperien and funded by the American Hospital Association. It provides a comprehensive view of the 340B program. Additionally, I wanted to make sure the record reflected the history of why the program was authorized in the first place.

In 1990, Congress created the Medicaid Drug Rebate Program. As you know, it requires pharmaceutical manufacturers to provide rebates for outpatient drug purchases, based on sales to Medicaid beneficiaries, as a condition of having their products covered by Medicaid. The amount of the rebates paid to the states were based on a "best price" calculation that did not take into account the discounted prices that manufacturers were offering directly to federally funded clinics and public hospitals serving large numbers of low-income and uninsured patients.

In 1992, Congressional hearings found that failing to exempt these voluntary discounts under the Medicaid Drug Rebate Program caused prices to rise for the facilities referenced above. The steep rise reflected the size of the discounts previously offered, and the shift once "best prices" were imposed in place of voluntary discounts. Consequently, Congress created the 340B program in November 1992 which protected specified clinics and hospitals ("covered entities") from drug price increases and gave them access to price reductions.

As you draft the report, I wanted to make sure you were aware of some of this past history and why the program was established.

Thank you,
Paul

<image002.png> **Paul Kidwell** <image002.png>
Senior Vice President, Policy
Phone 203.294.7247
E-mail kidwell@chime.org
110 Barnes Rd., Wallingford CT 06492

<image001.png> <image008.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

<image007.jpg>

The 340B Program: How it Delivers Value to Patients and Providers

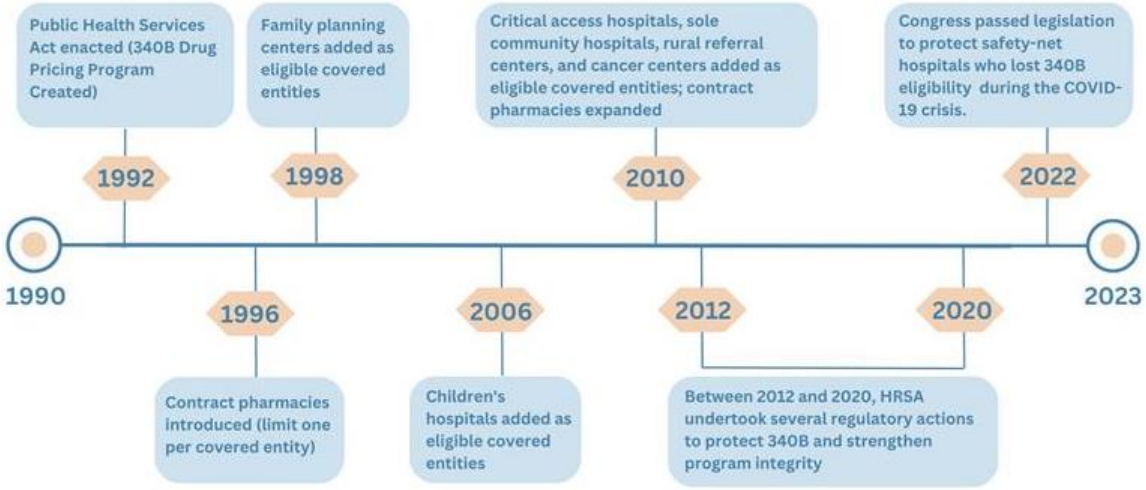
Over the past 30 years, the 340B Drug Pricing Program has played an essential role in ensuring health care providers have the necessary resources to provide vital programs and services for underserved patients and communities. Ongoing bipartisan support of the program is critical to ensuring continued access to needed care for patients. As drug prices continue to rise rapidly with advances in specialty pharmacy and biologics, 340B will become even more important to addressing access, affordability, health outcomes and disparities.

History of the 340B Program

In 1992, Congress created the 340B Drug Pricing Program as part of a strong bipartisan effort to protect hospitals and patients from the growing problem of rising drug costs. Lawmakers modeled the program after the Medicaid Drug Rebate Program, which protects state Medicaid programs from the high costs of drugs with limits on the amount those programs must pay. The 340B program adopted a similar approach to help certain hospitals stretch scarce resources to reach as many patients as possible and provide more comprehensive services at **no additional cost to taxpayers**. With the emergence of specialty drugs to treat chronic and acute conditions — and extensive patents protecting drug companies' abilities to price these drugs with limited to no competition — the 340B program has become an even greater resource for hospitals and their patients as they struggle to pay the high prices for many of these lifesaving drugs and treatments.

Serving as a crucial lifeline for 340B hospitals, the program mitigates health disparities and reduces health care costs while improving patient outcomes.[i] To ensure participation by pharmaceutical manufacturers, current law requires them to participate in the 340B program to receive Medicaid reimbursement. The Health Resources and Services Administration (HRSA) administers the 340B program and has developed strict rules and regulations to ensure program integrity consistent with the intent of Congress. Following the program's implementation and demonstrated success, Congress expanded it several times to allow more types of providers and their patients to access the benefit (**Figure 1**). HRSA has also repeatedly recognized the need to support facilities' access to drugs, especially those without in-house pharmacies, by allowing 340B providers to contract with external pharmacies to dispense drugs to patients on their behalf (see section below: **"The More You Know: Contract Pharmacies"**).

Figure 1: Major Legislative and Regulatory Actions of the 340B Program



Funding Provided by the American Hospital Association

How the 340B Program Works

The 340B program permits eligible providers, including hospitals and certain federal grantees, to enroll in the program and purchase certain outpatient drugs at a discounted price. Six types of hospitals are eligible for 340B: disproportionate share hospitals, rural referral centers, sole community hospitals, critical access hospitals, freestanding cancer hospitals, and freestanding children's hospitals. **Under current law, the 340B discounted price is 23.1% less than the price drug wholesalers pay to drug companies. However, the discount percentage can increase when drug companies decide to offer a lower price in the market than the 340B price or if they raise the price of a drug faster than the rate of inflation.** As a result, HRSA estimates the average discount is between 25% and 50%.[ii]

Due to this access to discounted drug prices, 340B eligible hospitals can achieve savings when purchasing drugs and use those savings to support care for underserved patients (**see Figure 2**):

Step 1: The drug manufacturer sets the outpatient drug's list price and then decides the price to sell to the wholesaler for hospital distribution. In the example below, the drug's list price is $120, and it is sold to the wholesaler for $100.

Step 2: The 340B hospital purchases the drug from the drug wholesaler at a lower price than that paid by non-340B hospitals. In the example below, the 340B hospital can purchase the drug at a 50% discount for a price of $50. However, had they not participated in 340B, the same hospital would have purchased the drug at a higher price, such as through a group purchasing organization (GPO) arrangement. In this example, the hospital not participating in 340B would pay the "GPO price" of $80.

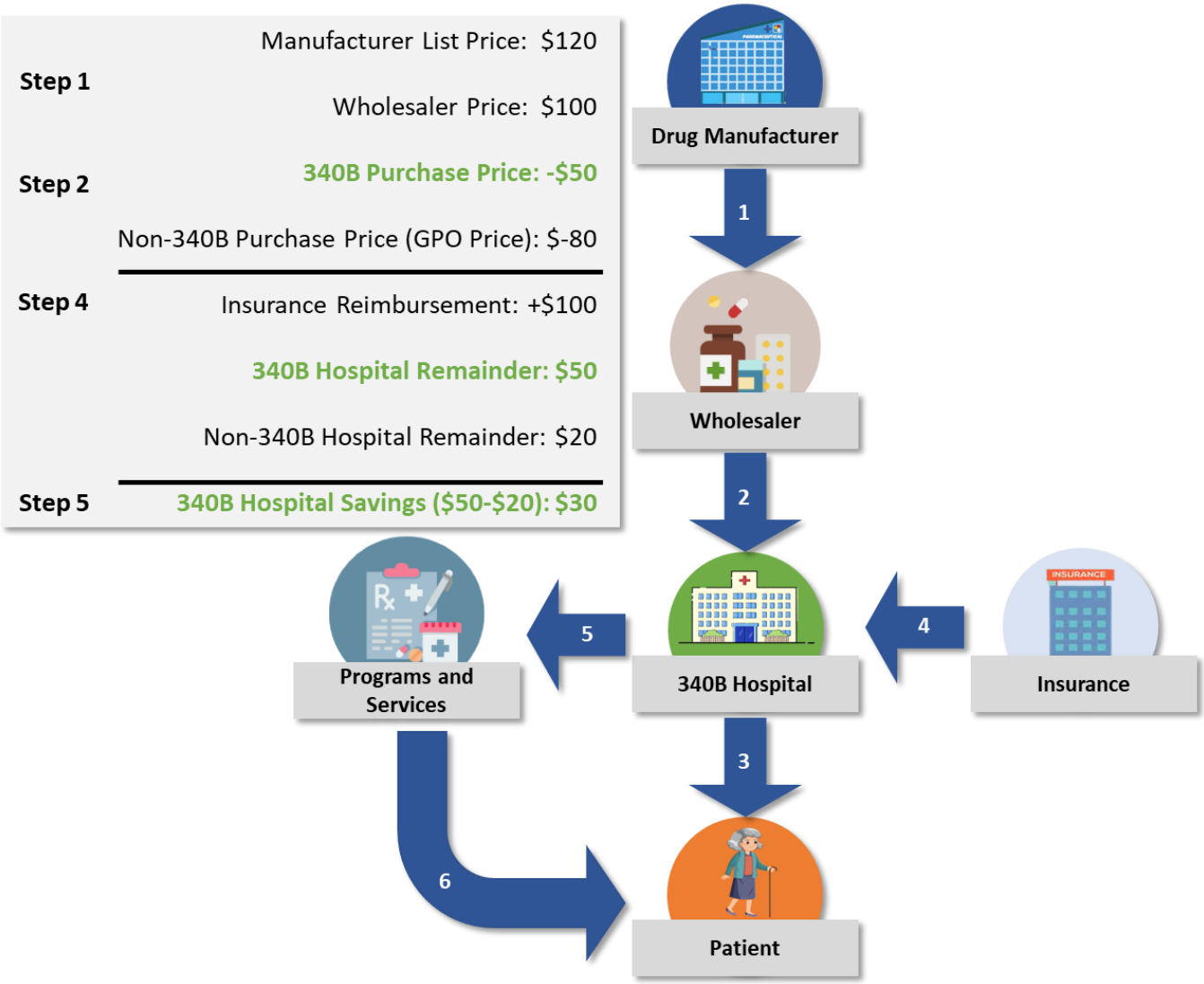
Step 3: Eligible patients receive the drug treatment through either the hospital's in-house pharmacy or a contracted community or specialty pharmacy.[iii]

Step 4: The hospital generates a claim for the drug provided to the patient and bills the patient's insurance — either a public or private payer — for reimbursement. **The reimbursement amount from either public or private payer is the same for both the 340B hospital and the non-340B hospital. In the case of public payers, these are fixed reimbursements for all hospital providers.** In the example below, payers reimburse the hospital $100 for the drug regardless of whether the hospital participates in 340B or not**.**

Step 5: The 340B hospital achieves savings because it purchased the drug at a lower price than it would have had it not been in the 340B program. In the example below, the savings are $30, or the difference between the 340B discounted price of $50 and the non-340B price of $80. These savings are then used to support critical programs and services.

Step 6: These programs and services supported by 340B savings directly benefit patients by improving their health outcomes, improving access to care, and reducing disparities in care. Examples of these services and programs include the provision of free or discounted drugs, behavioral health therapy services, and diabetes treatment clinics.

Figure 2: How the 340B Program Works



Value of the 340B Program to Hospitals

Hospitals increasingly face significant inflationary cost pressures from areas such as staffing and medical supplies; with drug price inflation adding to that burden.[iv] **In fact, drug companies increased the price of their drugs faster than inflation for over 1,200 drugs between July 2021 and July 2022, with an average price increase of 31.6% and several drugs experiencing over 500% price growth.**[v] In particular, specialty drugs — injectables and biologics — and oncology drugs continue to drive costs that outpace the rest of the health care services market.[vi] Additionally, price increases for nearly half of all Medicare outpatient drugs — 48% of 568 drugs — exceeded inflation in 2019 and 2020.[vii] Hospitals also face growing cost pressures amid chronic underpayments by Medicare and Medicaid for services more broadly, threatening their ability to provide access to needed care. As a result, many hospitals are at risk of closure or reduced service offerings due to their location and patient population — 340B is a critical lifeline.

Hospitals can use their program savings to maintain and, in many cases, expand access to care. The program allows each 340B hospital to best support the unique needs of the patients and communities they serve. For example, a small, rural hospital in West Virginia may use its 340B savings to support mobile treatment services for rural patients who cannot travel long distances for care. At the same time, an urban hospital in California may use its 340B savings to support a program that offers drug treatments free of cost for the local homeless population. **Because different hospitals and populations have different needs, Congress decided not to restrict how hospitals should use their savings.**

The More You Know: Contract Pharmacies

Some hospitals don't have in-house pharmacies, and if they do, they may serve patients who don't live in the immediate area. *To ensure patients have access to medications in the communities in which they live, 340B hospitals contract with community and specialty pharmacies to dispense drugs to these patients on behalf of the hospitals. Contract pharmacies provide an additional access point for patients to receive the drugs they need, including many specialty drugs that are often in limited distribution, without patients having to travel far distances. As a result, the hospital can ensure the patient gets the drug they need, improving adherence to drug treatments while also allowing the hospital to earn 340B savings. Therefore, these arrangements offer another way for 340B hospitals to provide comprehensive patient services and access to care as Congress intended in creating the program.*

Value of the 340B Program to Patients

The nation's underserved patient populations rely on the 340B program to address persistent access issues for a variety of critical health care services, including access to behavioral health, telehealth and free or discounted drugs. For example, nearly one-third of Americans report not taking medications as prescribed due to cost concerns.[viii] Moreover, many of these patients fall in the gap between Medicaid and fully insured, with limited options to assist them in affording needed health care services.[ix] 340B hospitals provide 77% of the nation's care for Medicaid patients.[x] Notably, benefits from the program help address disparities in care and health care outcomes for people living with disabilities and racial and ethnic minorities, particularly those in structurally marginalized communities who face disproportionate illness burdens and barriers to care.[xi] In 2019 alone, 340B hospitals provided nearly $68 billion in community benefits.[xii] At the same time, total 340B sales were approximately $30 billion, of which hospitals accounted for approximately 85% or $26 billion.[xiii] **That means for every dollar in 340B sales, 340B hospitals provided over two dollars in benefit to the patients and communities they serve.**

The 340B program plays an important public policy role in ensuring access to essential drugs and services for low-income and underserved Americans receiving care at 340B hospitals nationwide. Without the program, many patients could have trouble accessing affordable medications and critical health services, jeopardizing their health and well-being.

---

[i] L&M Policy Research. *Examination of Medicare Patient Demographic Characteristics for 340B and Non-340B Hospitals and Physician Offices*. July 2022.
[ii] Health Affairs. *The 340B Program*. 2017
[iii] *Note: In order for the 340B hospital to purchase the drug at a discounted price, the drug must be administered to a patient that had a medical visit with an employed or contracted provider of the 340B hospital. Otherwise, it must purchase the drug at the same price as a non-340B hospital.*
[iv] Kaufman Hall. *National Hospital Flash Report. December 2022.*
[v] Office of the Assistant Secretary for Planning and Evaluation. *Price Increases for Prescription Drugs, 2016-2022*. September 2022.
[vi] JAMA Network. *Trends in Prescription Drug Launch Prices, 2008-2021*. June 2022.
[vii] Kaiser Family Foundation. *Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020*. February 2022.
[viii] Kaiser Family Foundation. *KFF Tracking Poll*. February 2019.
[ix] Marshall University. *The 340B Program: Benefits and Limitations*. 2018.
[x] Health Affairs. *30 Years Of 340B: Preserving the Health Care Safety Net*. 2022
[xi] Health Affairs. *30 Years Of 340B: Preserving the Health Care Safety Net*. 2022
[xii] *2022 340B Hospital Community Benefit Analysis.* https://www.aha.org/system/files/media/file/2022/06/340b-community-benefits-analysis-6-3-22.pdf
[xiii] *FY2022 HRSA Budget Justification*. https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy20220.pdf

Novartis Corporation
Global Public Affairs
One Health Plaza
East Hanover, NJ 07936

https://www.novartis.com
https://twitter.com/novartisnews

Mehul Dalal, MD MSc
Chief Policy Advisor
Connecticut Dept. of Social Services
55 Farmington Ave.
Hartford, CT 06105

Dear Dr. Dalal,

Thank you for the opportunity to present to the 340B Working Group established by Connecticut Public Act 23-171, Section 16. As a follow-up to my presentation, I am submitting written comments for the Working Group's consideration.

Novartis provides health care solutions that address the evolving needs of patients and societies worldwide. We are a focused medicines company concentrated on the core therapeutic areas of cardiovascular disease, immunology, neuroscience, and oncology. At Novartis, we are united by a single purpose to reimagine medicine to improve and extend lives.

Novartis supports policy solutions that improve patient access to medicines, including policies that support the health care safety net. As a longstanding participant in the 340B program, we believe that the program can play a role in expanding health care access and affordability, particularly for low-income and under-insured or uninsured patients.

Nevertheless, lax federal oversight has caused the 340B program to grow rapidly and inappropriately, particularly in recent years, with no evidence that patients are benefiting accordingly. Once a small program, 340B has become the second largest federal drug program with discounted sales of almost $44B in 2021.[1]

Given the size of this program, and the well-documented corresponding rise in program integrity concerns, we believe reform -- at the federal level -- is essential to refocus the 340B program on its mission of enhancing patient access to affordable prescription medicines.

Growth of contract pharmacy arrangements benefits not just covered entities but also a robust ecosystem of for-profit entities.

Since 2010, the number of covered entity contracts with pharmacies has grown exponentially, with roughly 33,000 pharmacies participating in the program today.[2]

[1] Berkeley Research Group, 340B Program at a Glance, 2022. https://media.thinkbrg.com/wp-content/uploads/2022/12/06082105/340B-Program-at-a-Glance-2022_clean.pdf.
[2] PhRMA, How the 340B program became a PBM giveaway, December 11, 2023. https://phrma.org/Blog/How-the-340B-program-became-a-PBM-giveaway

NOVARTIS

Novartis Corporation
Global Public Affairs
One Health Plaza
East Hanover, NJ 07936

https://www.novartis.com
https://twitter.com/novartisnews

In Connecticut, 16 hospitals are part of the 340B program. Yet there are 1,401 contracts between Connecticut 340B hospitals and pharmacies nationwide, including some as far away as California, Nevada, Hawaii, and Texas.[3] Only 19% of contract pharmacies are located in medically underserved areas.[4]

Under these arrangements, contract pharmacies can share in 340B revenues with no strings attached — including charging an uninsured individual the full cost of the medicine — greatly benefitting these for-profit pharmacies financially.

Profits from contract pharmacy arrangements accrue not just to covered entities but also a robust ecosystem of for-profit entities, including third-party administrators, software vendors, and the contract pharmacies themselves, which are often a large pharmacy chain or aligned with a large vertically integrated pharmacy benefit manager (PBM).

More than half of the 340B profits retained by contract pharmacies are concentrated in four large, for-profit pharmacy companies: Walgreens, Walmart, CVS and Accredo (owned by Express Scripts).[5] In fact, both CVS Health and Walgreens have noted publicly in their earnings calls that 340B is a driver of their profits[6] and the research firm BRG has estimated that as much as $10 billion in profits will be captured by for-profit pharmacies this year.[7]

Additionally, PBMs often own, or are otherwise affiliated, with contract pharmacies. Today, 46% of contract pharmacy arrangements are with pharmacies affiliated with the three largest PBMs – OptumRx, CVS Caremark and Express Scripts.[8] PBMs also own the leading third-party administrators (TPAs) that covered entities use to adjudicate 340B claims.

States should not, and cannot, establish 340B contract pharmacy mandates for manufacturers.

“Contract pharmacies” are not mentioned anywhere in the federal 340B statute, and the notion of contract pharmacies was developed in 2010 solely through federal agency guidance that does not have the force and effect of law.[9] And, in establishing the 340B program, Congress did not provide for a role for states to define its parameters.

The federal government has a complex and pervasive statutory and regulatory regime in place that governs the 340B program and all its particulars. The program is nationwide, is

---

[3] HRSA, Contract Pharmacy Search Criteria page. https://340bopais.hrsa.gov/help/SearchViewExport/CP/ContractPharmacySearch.htm
[4] Xcenda, 340B and health equity: a missed opportunity in medically underserved areas, November 2021. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_issue_brief_340b_muas_nov2021.pdf
[5] BRG, For-Profit Pharmacy Participation in the 340B Program, October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf
[6] Drug Channels, or 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market, July 11, 2023. https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html
[7] BRG, 340B Program at a Glance, December 2022. https://media.thinkbrg.com/wp-content/uploads/2022/12/06082105/340B-Program-at-a-Glance-2022_clean.pdf
[8] PhRMA, How the 340B program became a PBM giveaway, December 11, 2023. https://phrma.org/Blog/How-the-340B-program-became-a-PBM-giveaway
[9] K&L Gates. 340B Update: HRSA Indicates It Lacks Authority to Enforce 340B Program Guidance. July 2020. https://www.klgates.com/340b-update-hrsa-indicates-it-lacks-authority-to-enforce-340b-program-guidance-7-21-2020

NOVARTIS

Novartis Corporation
Global Public Affairs
One Health Plaza
East Hanover, NJ 07936

https://www.novartis.com
https://twitter.com/novartisnews

administered nationwide, and applies nationwide. States that introduce a mandate on manufacturers different from the federal directives present a very real risk of creating an unmanageable "patchwork" of requirements for manufacturers subject to both those federal and state mandates.

Importantly, forcing manufacturers to extend 340B pricing to any contract pharmacy would further distort the 340B program. Yet, there is no evidence that the explosive growth in 340B contract pharmacies is benefiting patients accordingly:

- A report from the U.S. Government Accountability Office found that more than half of 340B hospitals surveyed did not share discounts with patients at their contract pharmacies.[10]
- The *Journal of the American Medical Association* released a study that found contract pharmacy growth from 2011 to 2019 was concentrated in affluent communities, as opposed to socioeconomically disadvantaged communities that 340B is intended to help.[11]

Instead, contract pharmacy arrangements divert program savings from their intended use – benefiting vulnerable patients – to increasing the profits of commercial middlemen (like PBMs). Further, the growth in contract pharmacy arrangements has come with concomitant growth in program integrity concerns.

Finally, Arkansas and Louisiana laws purporting to require manufacturers to provide 340B pricing through arrangements with pharmacies that contract with 340B hospitals and clinics are being challenged as unconstitutional in federal court.

Conclusion

Novartis appreciates the opportunity to provide our perspective on this critical safety net program. We welcome the opportunity to assist the 340B Working Group with its work moving forward.

Sincerely,

Daniel Vigil
Executive Director and Head, State Policy

[10] U.S. Government Accountability Office. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. Jun 2018. https://www.gao.gov/products/gao-18-480
[11] 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 https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530

Boehringer Ingelheim

Jennifer Herz
(860) 970-4404
Jennifer.Herz@
boehringer-ingelheim.com

SENT VIA EMAIL
Mehul.Dalal@ct.gov

Testimony: Connecticut 340B Workgroup

Dear Dr. Mehul Dalal and colleagues:

Boehringer Ingelheim submits this testimony to support the work of Connecticut's 340B Workgroup (the "Workgroup"). As you know, the Workgroup was established by Public Act 23-171, Section 16 and held three meetings on November 7, November 28 and December 19, 2023. Unfortunately, due to the condensed timeframe and holiday season, Boehringer was unable to provide either in-person or written testimony prior to the final meeting. In lieu of that, Boehringer respectfully submits this letter in an effort to share our expertise on this important topic.

Boehringer Ingelheim is working on breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need. Founded in 1885 and family-owned ever since, Boehringer Ingelheim takes a long-term, sustainable perspective. Our U.S. headquarters are in Ridgefield and home to our North America research hub with more than 2,100 employees.

Current 340B Program is not Helping Patients with Cost

The central issue with the current application of the 340B program is that it is often not helping eligible patients, but instead underwriting hospital systems and chain pharmacy budgets. The 340B program was originally established to support safety-net providers – essentially hospitals with a high low-income population of un-insured or under-insured patients. Boehringer Ingelheim and other manufacturers support the original intent of the program. Unfortunately, it has been taken advantage of by other players in the healthcare system, so it is no longer serving its original purpose. Rather, it has been abused and misused, particularly by hospitals and hospital systems to the detriment of other participants in the health care system including insurers, under-insured patients and cash-paying patients. "Starting in the mid-2000s, big hospital chains figured out how to supercharge the program. The basic idea: Build clinics in wealthier neighborhoods, where patients with generous private insurance could receive expensive drugs, but on paper make the clinics extensions of poor hospitals to take advantage of 340B" (New York Times: Profits Over Patients, *How a Hospital Chain a Used a Poor Neighborhood to Turn Huge Profits, Published Sept. 24, 2022, Updated Sept. 27, 2022; by Katie Thomas and Jessica Silver-Greenberg*).

340B Discounts – Where do they Go?

Theoretically, hospital systems and pharmacies purchase pharmaceutical products from manufacturers that participate in the 340B program at deeply discounted prices (essentially penny pricing) and then use that savings to invest in their communities. The purchasing of 340B discounted products was originally done by pharmacies on-site at the hospitals or other health care entities such as community clinics or a single contracted pharmacy if the entity did not have its own "in-house" pharmacy. However, that is not the current practice, as the access and purchasing of 340B discounted products has exploded. Entities are instead using the spread of the 340B discounted pricing on the products they purchase and what they charge patients to meet their own budget needs. This point is demonstrated clearly by the exponential growth of contract pharmacies since 2010, when HRSA issued guidance claiming to allow covered entities participating in the 340B program to have unlimited contract pharmacies. And it's important to note that the program currently has no patient protection requirements and no requirements for hospitals to use any profit through the 340B program to help patients afford their medicine.

Our Ask

We support the original application of the 340B program as one of many tools manufacturers use to ensure access to much needed health care services for low-income patients. However, the 340B program is being exploited by large entities for their own benefit. As the USC Schaeffer White Paper concluded: "this [340B] program is unusual among federal programs in that it involves a mandatory transfer of resources from one group of private entities (manufacturers/wholesalers) to another (providers)." To that point, an American Medical Journal article in June of 2022 found that from 2011 to 2019, the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic, black, and Hispanic/Latino communities declined while the share of 340B pharmacies in the highest-income neighborhoods increased.

Since 340B is a federal program we, along with other manufacturers, are working on the federal level for a solution that continues to support patients. It is noteworthy that the federal coalition working to ensure the 340B program supports true safety-net providers and the communities they serve - called ASAP 340B - includes the National Association of Community Health Centers as well as drug manufacturers including Boehringer, among other patient and provider organizations. This group represents stakeholders throughout the health care ecosystem all committed to the common goal of returning this program to its original intent: benefitting un-insured and under-insured patients. Boehringer supports these efforts and the development of federal program standards and enforcement.