Opposition to Minnesota 340B legislation

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The Facts: 340B Program Impacts in Minnesota

340B program legislative proposals in Minnesota are less about patients and more about boosting the bottom lines of hospitals and chain pharmacies predominantly owned by middlemen, known as pharmacy benefit managers (PBMs).

Did you know? *Minnesota 340B hospitals have nearly 2,200 contracts with pharmacies, nearly 1,200 of which are located outside the state. Vertical integration in the supply chain has enabled for-profit middlemen like PBMs and chain pharmacies to game the system and profit from a federal safety-net program.*

Myth: The 340B program does not cost Minnesota taxpayers any money.

FACT: Not only does the 340B program raise prescription drug costs for Minnesotans with employer insurance, it also raises the cost of state health programs, like the state employee health plan, which are funded by taxpayers.

While it is true that the program is not directly funded by taxpayers, all Minnesotans are indirectly footing the bill for the program.

- Because deductibles and coinsurance are typically based on the cost of a patient's prescriptions, the prescribing patterns of 340B hospitals can lead to higher cost sharing for some patients[1] and could even drive-up premiums[2] for all commercially insured patients.
- A new analysis from the Medicare Payment Advisory Commission found Medicare and people enrolled in Medicare Part B are overpaying by 50% for Part B medicines dispensed through the 340B program.[3]
- A recent study by IQVIA found that "the 340B program increases drug costs for self-insured employers and their workers by 4.2%", which "corresponds to a $5.2B increase in healthcare costs for self-insured employers.[4]

Myth: Contract pharmacies are paid a nominal dispensing fee from 340B-covered entities.

FACT: While some contracts include provisions for the hospital to pay the contract pharmacy a flat fee for each eligible prescription, many pay pharmacies a percentage of revenue generated by each prescription.[5] Regardless of how they are compensated, contract pharmacies generate significant revenue and are not required to use that revenue to lower costs for patients.

The average profit margin on 340B prescriptions commonly-dispensed through contract pharmacies is 72% compared with just 22% on non-340B prescriptions dispensed through independent pharmacies.[6] **More than 50 cents of each $1 in profits contract pharmacies receive through the 340B program go to just four PBM and pharmacy companies — Walgreens, Walmart, CVS Health and Express Scripts.**

One publicly available pharmacy agreement[7] between a 340B hospital and a contract pharmacy shows a prescription for a specialty medicine has the potential to yield a gross margin of 16% when the contract pharmacy is

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[1] Hunter, Michael, Holcomb, Katherine. Milliman. "Analysis of 2020 commercial outpatient drug spend at 340B participating hospitals," September 13, 2022. https://www.milliman.com/en/insight/2020-outpatient-drug-spend-at-340b-hospitals
[2] Masia, Neal. AIR340B. "340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019." https://340breform.org/wp-content/uploads/2021/05/AIR340B-Neal-Masia-Report.pdf
[3] MEDPAC. "Initial finding from analysis of Medicare Part B payment rates and 340B ceiling prices." April 12, 2024. https://www.medpac.gov/wp-content/uploads/2023/10/340B-ceiling-prices-April-2024-SEC.pdf
[4] Sun, C., Zeng, S. Martin, R. IQVIA. "The Cost of the 340B Program Part 1: Self-Insured Employers." https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-part-1-self-insured-employers
[5] U.S. Government Accountability Office. "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." June 21, 2018. https://www.gao.gov/products/gao-18-480
[6] BRG. "For-Profit Pharmacy Participation in the 340B Program." Oct. 2020. https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/
[7] Jackson Health System. "Public Health Trust Board Meeting Agenda." March 23, 2016. https://www.jhsmiami.org/WebApps/publicDocs/docLib/PHT_BOT_Meetings_Prior/PHT_BOT_OneDayCommittee/2016-03-23%20-%20PHT%20BOT%20ONE-DAY%20COMMITTEE%20MEETINGS%20AGENDAS.pdf

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paid based on a percentage of the product's list price plus a $65 dispensing fee.[8] **Thus, a $5,000 specialty prescription will yield $815 in gross profit (16% gross margin) for the contract pharmacy, which has no obligation to use that profit to benefit patients.**

Myth: Patients pay less for their prescription medicines because of the 340B program.

FACT: **Numerous studies from independent watchdogs found no clear evidence the 340B program benefits low-income patients.**[9] This is because hospitals, pharmacies and many participating clinics aren't required to, and often don't, pass along the 340B discounts they receive on medicines directly to patients to reduce the cost of the patients' medicines. There's no way to know where the money is going.

Some 340B medicines from manufacturers are so heavily discounted that hospitals can buy the medicine for *one penny*, but patients have no guarantees they will see these savings. In fact, 340B providers can turn around and bill the patient (and their plan provider) for the full list price of the medicine and existing proposals in Minnesota will not change this to further protect patients.

340B hospitals also prescribe more and more expensive medicines than non-340B hospitals, driving up costs for patients. According to a recent study in the New England Journal of Medicine, 340B hospitals collect seven times as much as independent physician offices for the sale of medicines administered to commercially insured patients, and they charged commercial insurers prices that were 289% more than those charged by independent physician offices.

Myth: Drug manufacturers are denying covered entities 340B discounts.

FACT: Manufacturers are required by law to give discounts on medicines purchased by the entities listed in the 340B statute: qualifying hospitals and clinics participating in the 340B program. Some manufacturers have individually decided to limit the shipment of 340B-discounted medicines to offsite pharmacies, known as "contract pharmacies," that have never been included in the statutory scheme since Congress created it.

The biopharmaceutical industry supports the original goals of the 340B program as it has since it first became law in 1992. We want the program to work as intended to support low-income and vulnerable patients, not hospital, PBM, or pharmacy bottom lines.

Myth: Hospitals' use of contract pharmacies increases access for patients' medicine

FACT: In Minnesota, just 35% of pharmacies contracting with 340B providers are in medically underserved areas.[10] Additionally, 81% of 340B hospitals in Minnesota are below the national average for charity care levels. In total, hospitals in Minnesota make 8.2 times as much from 340B as they spend on charity care.

The 340B proposals facing Minnesota policymakers today would allow unrestrained use of contract pharmacies — meaning PBMs could continue to game the system for patient dollars from 340B.

Vote NO on these 340B proposals to put the needs of vulnerable Minnesotans above the financial interests of for-profit corporations.

[8] Fein AJ. "Drug Channels News Roundup." January 30, 2024. https://www.drugchannels.net/2024/01/drug-channels-news-roundup-january-2024.html.
[9] NEJM. "Consequences of the 340B Drug Pricing Program." January 24, 2018. https://www.nejm.org/doi/full/10.1056/NEJMsa1706475
[10] BRG. "Analysis of HRSA OPAIS Database and Medicare Cost Reports." https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/50-State-340B-Fact-Sheets/Fact-Sheet---340B-State-Profiles---Minnesota---2024.pdf

IQVIA Research Summary

The Cost of the 340B Program Part 1: Self-Insured Employers

CHUAN SUN, MS, MA, IQVIA Market Access
SHANYUE ZENG, MA, IQVIA Market Access
RORY MARTIN, PHD, IQVIA Market Access

Key Points

Importance: The 340B program is sometimes described as something that does not cost taxpayers anything. Given its rapid evolution in terms of legislative changes, changes in pharmaceutical industry practice, and judicial decisions, it is important to understand its true cost.

Objective: This IQVIA study estimated the cost of the 340B program to self-insured employers. These entities employed 103.4M non-elderly individuals in the U.S. in 2021.

Design: IQVIA built a financial model to quantify the financial impact of the 340B program on healthcare costs. The model included 340B eligibility, manufacturer rebates, and lost rebates due to product purchased through the program.

Data sources: IQVIA estimated model parameters using national samples of consumers, payers, products, and providers.

Results: The model estimated drug costs for self-insured employers and their workers are 4.2% higher than they otherwise would have been if the program did not exist due to lost rebates. This corresponds to an annual increase of $5.2B in healthcare costs for self-insured employers and their workers.

Conclusions: In light of these findings, the narrative that "the 340B program costs taxpayers nothing" should be reconsidered. If the same rebate dynamic is true for Medicare and Medicaid, the 340B program may also be increasing costs for state and federal programs.

Employers and workers pay more for drugs when 340B is used, but hospitals profit. A self-administered drug costing $100 at WAC is purchased without the 340B program (left-hand side) and using the 340B program (right-hand side).

The full IQVIA white paper can be found here.

CONTACT US
iqvia.com

BY THE NUMBERS: 340B IS DRIVING UP HEALTH CARE COSTS

The 340B Drug Pricing Program was designed to help vulnerable patients access medications at safety-net facilities. Since the program was created in 1992, manufacturers have provided tens of billions of dollars each year in steep discounts on outpatient medicines to safety-net clinics and qualifying hospitals expecting those entities would use the savings to ensure vulnerable patients have access to needed medicines. But the 340B program has strayed far from its safety-net purpose. Instead, it creates incentives that drive up health care costs and it boosts the bottom lines of hospitals and for-profit pharmacies instead of helping patients.

Here's a look at how 340B is driving up patient costs, by the numbers:

The prescribing practices of 340B hospitals are driving up costs for patients, payers and the health care system as a whole.

7X

340B hospitals collect 7 times as much as independent physician offices for the sale of medicines administered to commercially insured patients.

150%

The average cost of an outpatient medicine administered at a 340B hospital was more than 150% higher than the average cost of an outpatient drug administered at a non-340B hospital.

$5.2B

340B increases medicine costs for self-insured employers by 4.2%, relative to if the program didn't exist. This translates into annual increased health care costs of $5.2 billion.

There is little evidence that the 340B program is improving health care access for patients most in need.

65%

An analysis found 65% of 340B disproportionate share hospitals (DSH) provide less charity care than the national average for all hospitals.

1.4%

An analysis of contract pharmacy claims for brand medicines only found evidence that patients were directly receiving a discount for 1.4% of prescriptions eligible for 340B.

38%

Multiple studies confirm that the expansion of 340B entities tends to be in less diverse, higher income neighborhoods – not in areas with high unmet medical needs. Just 38% of 340B DSH hospitals are in medically underserved areas.

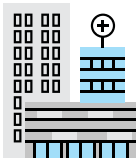
For-profit companies and large consolidated hospital systems benefit more from 340B than patients.

50%+

More than half of the top 20 companies on the Fortune 500 generate profit from 340B.

37%

340B nonprofit hospitals' average profitability was estimated to be 37% higher than the average across all hospitals.



After factoring in the steep 340B manufacturer discounts, the net price 340B hospitals pay for medicines can be as low as one penny. The problem? The difference between the gross price and net price is kept by hospitals and others in the supply chain. We need to fix 340B so it helps more patients as it was originally intended.

Learn more at **PhRMA.org/340B**

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How the 340B Program Became a PBM Giveaway

In 1992, the federal 340B drug pricing program was created for certain safety-net hospitals and clinics (like community health centers) to help low-income and otherwise vulnerable patients more affordably access medicines. Flash forward to today, and you'll find pharmacy benefit managers (PBMs) have found a way to siphon money out of the program for their own financial benefit.

The 340B program works by letting hospitals and clinics buy outpatient medicines at a reduced price. Hospitals often still charge patients and insurers based off an undiscounted price of medicines though – meaning they are reimbursed at a higher price than they paid for the medicine. **Hospitals pocket as profit the difference between the amount they are reimbursed and the discounted 340B price they paid.**

While pharmacies were not mentioned in the law, today they are also profiting from the program by contracting with 340B hospitals and clinics. **These contract pharmacies leverage their arrangements within the 340B program to boost their own bottom lines because they share in any profit hospitals generate from 340B medicines.** These contract pharmacies have even been known to charge uninsured patients the full cost of a medicine even if the hospital bought it for the contract pharmacy at a 340B discount.

Today, **large pharmacy corporations have flooded the program.** Currently, over 33,000 distinct pharmacies participate in the 340B program. More than half of all 340B profits retained by contract pharmacies are concentrated in four companies: Walgreens, Walmart, CVS and Accredo.

That's where PBMs come in. Because of vertical integration in the supply chain, PBMs now own the vast majority of pharmacies, meaning they also make a profit from contract pharmacy arrangements.

- Today, 46% of contract pharmacy arrangements are between 340B covered entities (hospitals and clinics) and pharmacies affiliated with one of the three largest PBMs (ESI, Optum, Caremark).
- The big three PBM-owned specialty pharmacies account for 26% of contract pharmacy arrangements.
- Nearly half of the top 25 companies on the Fortune 50 today generate profit from 340B.

Policymakers should be asking themselves: How did a program meant for safety-net hospitals and clinics become a PBM giveaway?

Comprehensive fixes are needed to make the 340B program work better for patients, and that includes policies that prevent for-profit corporations like PBMs from profiting off the program. Read more about our proposed changes here.

Learn more at PhRMA.org/340B

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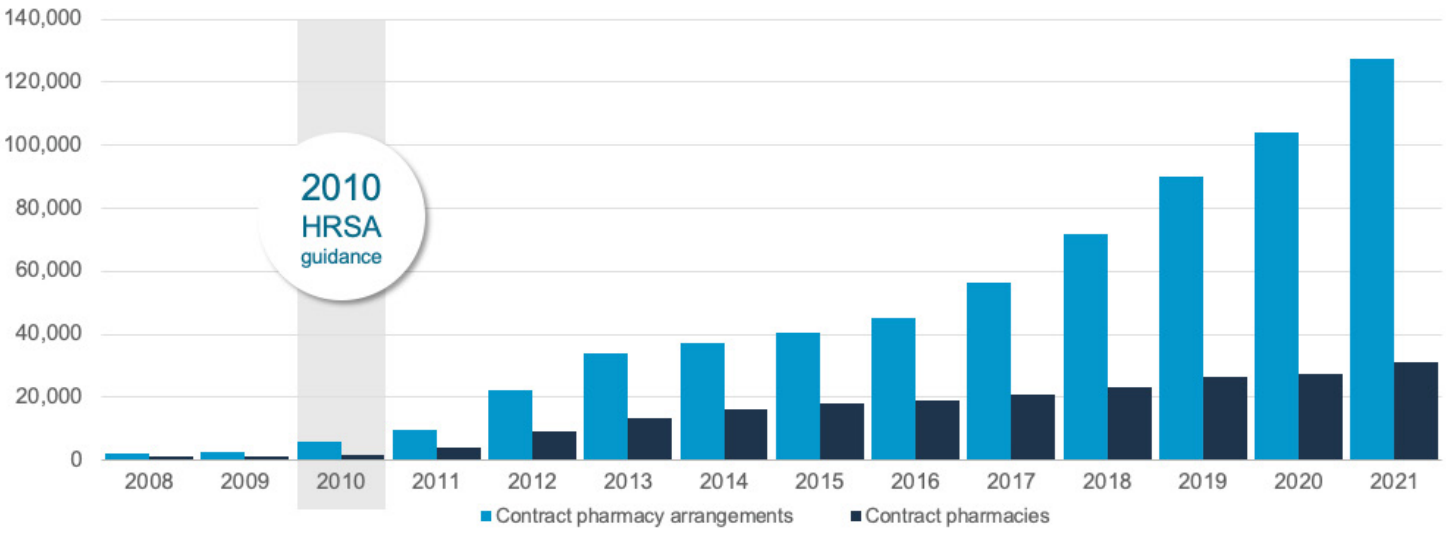
340B Contract Pharmacy Participation Has Increased Dramatically

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

340B Hospital Contract Pharmacies and Pharmacy Arrangements*



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

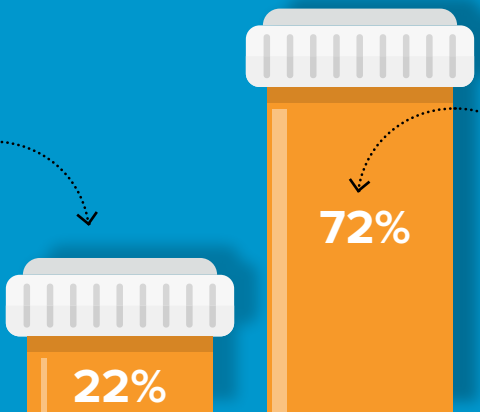
Learn more at PhRMA.org/340B

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

Contract Pharmacies Have Growing Financial Stake in 340B

There is no clear evidence 340B discounts are helping patients access medicines.

Massive Profit Margins



340B medicines dispensed through contract pharmacies

Non-340B medicines dispensed through independent pharmacies

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

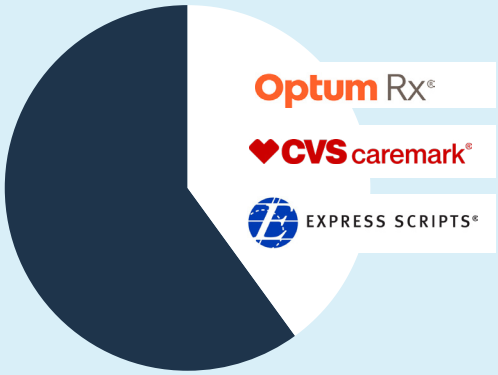
Concentrated Corporate Profits

>50%

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

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

PBM-Owned Pharmacies Wield Negotiating Power



40% of arrangements are between 340B entities and pharmacies **associated with one of the three largest PBMs**

Drug Channels analysis of HRSA Office of Pharmacy Affairs daily contract pharmacy database. Published April 2022.

Learn more at PhRMA.org/340B

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A Closer Look at 340B in Your Community

The 340B Drug Pricing Program was designed to help vulnerable patients access medications they might not be able to afford. To achieve this, manufacturers provide tens of billions of dollars each year in steep discounts on outpatient medicines to safety-net clinics and qualifying hospitals. The expectation is that those entities would use those savings to ensure vulnerable patients' access to medicines.

But the 340B program is broken. Today, it has become less about patients and more about boosting the bottom lines of hospitals and for-profit pharmacies, which are mostly owned by middlemen, known as pharmacy benefit managers (PBMs).

Here's what the program looks like across the country and in Minnesota.

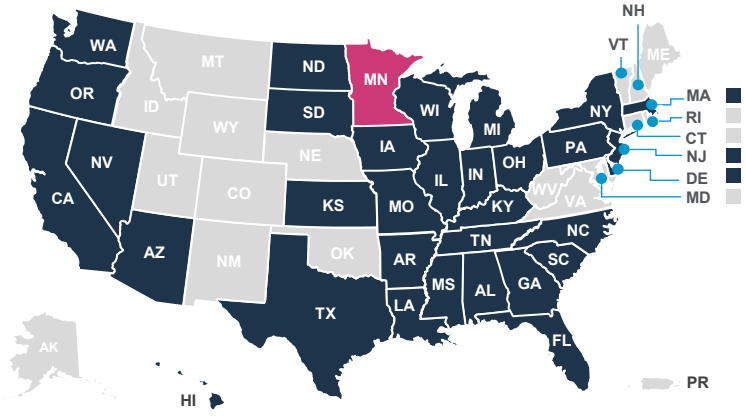
Fast Facts: 340B Nationwide

- 57% of all hospitals in the United States participate in the 340B program.
- Discounted 340B purchases reached nearly $54 billion in 2022 nationwide – 23% higher than in 2021.
- The number of contract pharmacies has grown nationwide by more than 8,000% since 2010.
- 46% of contract pharmacy arrangements are with pharmacies associated with one of the three largest PBMs.

Fast Facts: 340B in Minnesota

- 113 hospitals in Minnesota are part of the 340B program.
- 2,173 contracts between Minnesota 340B hospitals and pharmacies nationwide.
- Only 35% of contract pharmacies are located in medically underserved areas.
- 81% of 340B hospitals in Minnesota are *below* the national average for charity care levels.

Locations of 340B Contract Pharmacies – and Middleman Involvement – in Minnesota, 2023



Did you know that Minnesota 340B hospitals have nearly 1,200 contracts with pharmacies outside the state? Because of vertical integration in the supply chain, for-profit middlemen like PBMs and chain pharmacies also now make a profit from this safety-net program.

Are Minnesota's 340B hospitals providing adequate charitable care?

- Charitable care is the free or reduced-cost care provided to qualifying patients.
- Unfortunately, 77% of nonprofit hospitals nationwide spent less on charity care than they gained from tax breaks.
- The top performing 340B hospitals nationwide collected nearly $10 in total profit for every $1 they invested in charity care in 2021.
- In Minnesota, the charity care rate at 340B hospitals is 0.8%. This is below the national average of 2.5% (which includes both 340B and non-340B hospitals).
- In total, hospitals in Minnesota make 8.2 times as much from 340B as they spend on charity care.

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Learn more at **PhRMA.org/340B**

BRG Analysis of HRSA OPAIS Database and Medicare Cost Reports. October 2023

For-Profit Pharmacies Make Billions Off 340B Program Without Clear Benefit to Patients

A recent Berkeley Research Group analysis explored the staggering side effects of contract pharmacy expansion on the 340B program over the past 10 years. The misguided guidance that allowed 340B entities to contract with an unlimited number of for-profit retail pharmacies ultimately allowed for-profit vendors, pharmacies and pharmacy benefit managers to exploit the program.

$13 Billion

generated in estimated gross profits for 340B covered entities and their contract pharmacies from 340B purchased medicines in 2018.

>5,000%

growth in contract pharmacy arrangements since 2010.

>50%

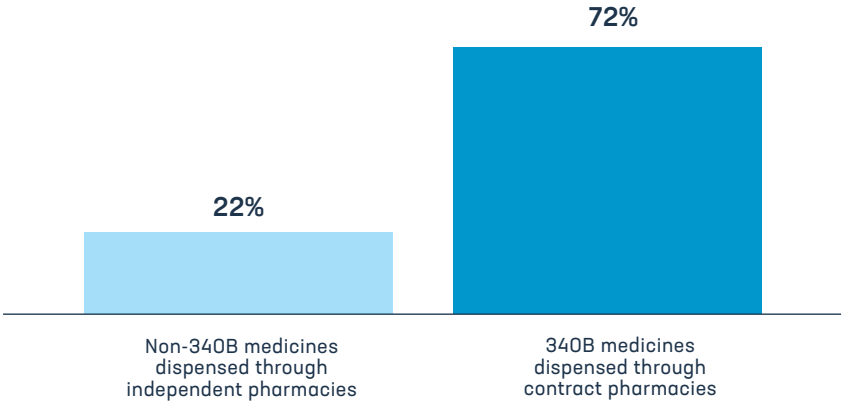
of 340B profits generated by contract pharmacies are retained by four for-profit corporations.

Here's an example of how it works:

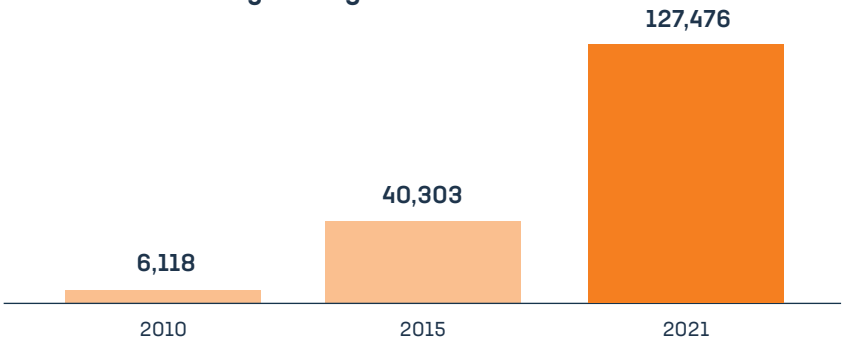
- Uninsured patient gets sick
- Uninsured patient gets treated at a 340B hospital
- Patient goes to 340B contract pharmacy and fills prescription at full retail price (example: $100)
- Afterward, the hospital gets a discount (example: $50 though it could be higher) from drug manufacturer, which it can share with the pharmacy

Patient often doesn't see any of the discount

Average Profit Margin



Contract Pharmacy Arrangements



Berkeley Research Group, "For-Profit Pharmacy Participation in the 340B Program," October 2020.
Berkeley Research Group analysis of Health Resources and Services Administration Office of Pharmacy Affairs registrations, January 2022.

Reforms are needed to ensure the program reaches the vulnerable and uninsured patients it was intended to help.

Learn more at PhRMA.org/340B

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STATEMENT

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In Opposition to Minnesota House Senate File 5301 Article 3, Section 3
340B Contract Pharmacy Mandate
April 2024

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes Article 3, Section 3 included in Minnesota Senate File 5301 (SF 5301). SF 5301 would require biopharmaceutical manufacturers to ship 340B drugs to all pharmacies that contract with 340B "covered entities" and by extension offer 340B pricing at these locations. This type of provision not only raises constitutional concerns, but also exacerbates existing problems with the 340B program without ensuring that vulnerable patients needing discounted medicines will benefit.

Additionally, the Minnesota Department of Health just received initial data from 340B health care entities the beginning of April 2024 that the state is currently evaluating. The Minnesota Legislature should evaluate this data before enacting additional legislation related to the 340B program.

SF 5301 would mandate that manufacturers ship 340B drugs to all pharmacies that contract with 340B covered entities and by extension offer 340B pricing at these locations.

The 340B program is a comprehensive federal program that is governed exclusively by federal law. States do not have the authority to create new requirements that are not in the federal statute or that conflict with the statute. Whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers is currently being litigated in several federal courts across the country.

At least three cases have found that the 340B statute is silent on how drugs must be distributed under the 340B program, which supports the assertion that the statute does not require any specific action with respect to covered entities' contract pharmacies. In January 2023, the U.S. Court of Appeals for the Third Circuit held that "[s]ection 340B [of the federal statute] does not require delivery to an unlimited number of contract pharmacies" and "Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies." *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs*., 58 F.4th 696 (3d Cir. 2023).

Despite the ongoing legal activity at both the federal agency and in the federal courts, Arkansas and Louisiana have enacted legislation similar to SF 5301 that have serious constitutional defects and are being challenged in federal court.

Congress created the 340B drug discount program in 1992 to help vulnerable and uninsured patients access prescription medicines at safety-net facilities.

Through the program, biopharmaceutical manufacturers provide tens of billions of dollars in discounts each year to qualifying safety-net hospitals and certain clinics ("covered entities"), but patients are often not benefitting. Today, large hospital systems, chain pharmacies, and pharmacy benefit managers (PBMs) are generating massive profits from the 340B program even though its intended beneficiaries were true safety-net hospitals and clinics and the low-income and vulnerable patients they treat. The 340B program has

strayed far from its safety-net purpose, and Congress needs to fix the program to ensure that it is reaching its intended populations.

There is little evidence to suggest that patients have benefited from contract pharmacy growth.

An analysis of contract pharmacy claims for brand medicines only found evidence that patients were directly receiving a discount for 1.4% of prescriptions eligible for 340B. Additional studies have found that 65 percent of the roughly 3,000 hospitals that participate in the 340B program are not located in medically underserved areas,[1] and in Minnesota, only 35% of contract pharmacies are located in medically underserved areas. Research has also found that more than two-thirds of 340B hospitals provide less charity care than the national average for all hospitals, and they often spend less on charity care and community investment than the estimated value of their tax breaks as nonprofits. In fact, 81% of 340B hospitals in Minnesota are below the national average for charity care levels.

The prescribing practices of 340B hospitals are driving up costs for patients, payers, and the health care system as a whole.

Based on a recent analysis by IQVIA, the 340B program increased drug costs for self-insured employers and their workers by 4.2% or $5.2 billion due to the manufacturer rebates that are lost when drugs are purchased at the 340B discounted price.[2] Increased drug costs for employers and their workers from the 340B program is a result of 340B hospitals collecting the spread between the price they are reimbursed by insurers and patients and the discounted 340B price they paid for their medicines. Thus, the claim that "the 340B program costs taxpayers nothing" is inaccurate if it is driving up the cost of prescription drugs for employers and their workers.

SF 5301 will line the pockets of PBMs, pharmacy chains, and large hospitals.

Since 2010, the number of contracts with pharmacies has grown by more than 8,000%, with roughly 33,000 pharmacies participating in the program today. Many contract pharmacies may often charge a patient a drug's full retail price because they are not required to share any of the discount with those in need.[3] Big-box retailers such as Walgreens, CVS Health, and Walmart are major participants in the 340B program through contract pharmacy arrangements. Because of vertical integration in the supply chain, PBMs now own the vast majority of pharmacies, meaning they also make a profit from contract pharmacy arrangements. In fact, the five largest for-profit pharmacy chains comprise 60 percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide.[4] 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018, which represents more than 25% of pharmacies' and providers' total profits from dispensing or administering brand medicines.[5]

PhRMA respectfully opposes Article 3, Section 3 included in SF 5301 and asks the Committee to strike that language from the bill.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.

[1] Alliance for Integrity & Reform. "340B – A Missed Opportunity to Address Those That Are Medically Underserved." 2023 Update. Access: https://340breform.org/wp-content/uploads/2023/07/340B_MUA_July23-4.pdf.
[2] Chuan, S., Shanyue, Z. & Martin, R. The Cost of the 340B Program Part 1: Self-Insured Employers. IQVIA. Mar. 2024. https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-part-1-self-insured-employers.
[3] Conti, Rena M., and Peter B. Bach. "Cost consequences of the 340B drug discount program." *Jama* 309.19 (2013): 1995-1996.
[4] Government Accountability Office, "*Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*," GAO-18-480, June 2018.
[5] Berkeley Research Group. For-Profit Pharmacy Participation in the 340B Program. October 2020.

CORNERSTONE RESEARCH
Economic and Financial Consulting and Expert Testimony

30 JANUARY 2024

5 Questions with Sayeh Nikpay: The 340B Drug Pricing Program

A periodic feature by Cornerstone Research, in which our affiliated experts, senior advisors, and professionals, talk about their research and findings.

We interview Professor Sayeh Nikpay of the School of Public Health, University of Minnesota, to gain her insights into the 340B program, its role in the healthcare safety net, implementation challenges, and related legal matters.

The 340B program is an active area of research and litigation that is top of mind for policymakers and lawmakers. Can you give us an overview of this program?

The 340B Drug Pricing Program is a federal program that allows qualifying providers (also known as covered entities) to buy discounted outpatient prescription drugs and bill insurers to generate revenue to expand care for low-income and uninsured patients. Specifically, this program can generate revenue for covered entities because discounts for prescriptions dispensed to privately insured or Medicare patients are not typically reflected in insurer reimbursement rates for prescription drugs. That is, covered entities can purchase discounted prescription drugs and bill insurers at higher rates that do not reflect these discounts.

The 340B program intends to "enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services." In other words, the federal government hopes that covered entities will use 340B revenues to expand care for safety-net patients through programs and services that are typically unprofitable, such as community health improvement, obstetrics, or substance abuse care. However, there is no explicit requirement to do so, and the federal government does not track 340B revenues.

Covered entities that are allowed to participate in the 340B program include hospitals that serve a large proportion of Medicaid or low-income Medicare patients (also known as Disproportionate Share Hospitals), certain types of rural hospitals, cancer hospitals, pediatric hospitals, and various federally supported safety-net clinics such as Federally Qualified Health Centers (FQHCs). Whether covered entities pass on discounts to their safety-net patients remains unknown. While many federally supported clinics are required to provide discounted care on a sliding fee scale, hospital covered entities face no such requirements.

Covered entities can only dispense outpatient prescription drugs purchased through the 340B program to "eligible patients." The Health Resources and Services Administration (HRSA) defines eligible patients to be those who:

1. Have an established relationship with the covered entity (e.g., the covered entity maintains the patient's healthcare records),
2. Have received healthcare services from a healthcare professional employed by the covered entity, and
3. Have received healthcare services consistent with services that the covered entity typically offers. Eligible patients can receive outpatient prescription drugs purchased through the 340B program at the covered entity's outpatient clinics (called child sites), in-house pharmacies, or contract pharmacies, which are external pharmacies that contract with the covered entity.

How has the 340B program expanded over time?

Since 2010, the number of drugs dispensed under the 340B program has grown dramatically. Two major program changes led to this increase. First, the Affordable Care Act (ACA) expanded the types of covered entities that qualify for the 340B program. After 2010, critical access hospitals, sole community hospitals, rural referral centers, and freestanding pediatric and cancer hospitals became eligible. This expansion, driven primarily by the participation of critical access hospitals, increased the percentage of hospital covered entities from 10% in 2004 to over 60% in 2020.

Second, the HRSA issued guidance allowing covered entities to establish unlimited contract pharmacies. Before 2010, covered entities without an in-house pharmacy could only contract with one external pharmacy. After the limit was removed, the number of contract pharmacies participating in the 340B program increased more than tenfold. Current 340B revenues are estimated to be over $50 billion.

You are a health policy expert with deep knowledge of healthcare safety-net programs. Based on your research, can you explain why the 340B program has become controversial?

Expanding the 340B program has raised questions about whether it is being used as Congress intended. If hospital covered entities generate significant revenue by dispensing drugs purchased through the 340B program to privately insured or Medicare patients yet fail to increase access and care for safety-net patients, the program is not functioning as intended.

My research finds that the 340B program creates perverse incentives for covered entities. I have used large, nationally representative, administrative datasets to show that:

1. Hospitals that begin participating in the 340B program do not meaningfully increase their safety-net engagement.
2. The 340B program's eligibility criteria poorly target safety-net providers.
3. Contract pharmacies are less likely to be located in medically underserved areas, or areas with higher uninsured rates.

Additionally, in one of my recent publications, I show that nearly half of all retail pharmacies have at least one contract with a 340B covered entity. The number of contracts per pharmacy has grown over time. However, these 340B contract pharmacies are less likely to contract with hospitals and clinics that care for many patients who rely on the safety-net. In forthcoming research, I also find a large share of retail contract pharmacies concentrated among the four retail pharmacy chains with the highest market share by prescription volume.

What are some proposed changes that policymakers can enact to help the 340B program better serve its intended purpose?

One proposed change would be to define program eligibility criteria better, so 340B discounts primarily benefit covered entities that serve safety-net patients. For example, the criteria currently used to qualify hospitals for the program are not based on uninsured patient volume, charity care, or community benefit spending. As a result, the same 340B discounts can be provided to hospitals—regardless of their safety-net engagement—as long as the hospital qualifies as a covered entity. Better aligning the program's eligibility with demonstrated care for the uninsured and charitable care can strengthen the healthcare safety-net and improve access for patients who rely on it.

Another proposed change is to increase transparency and oversight of the 340B program. As I discuss above, 340B hospitals are not required to report revenues generated by the program, nor compelled to demonstrate how they use the generated revenue to expand care for safety-net patients. Because of the lack of transparency and oversight, it is unclear whether the hospital covered entities are using the discounts as Congress intended. Mandating that all covered entities regularly report average prices paid for 340B drugs, their programs' savings, how the savings are used, and the patients/programs served from the savings would improve oversight and shed light on whether the program is improving care for low-income patients. New legislation passed in both Maine and Minnesota in the summer of 2023 established transparency requirements for covered entities in those states.

The 340B program has been at the center of legal challenges involving drug manufacturers. Why are manufacturers concerned about the program's expansion?

Manufacturers must provide 340B discounts if they want Medicaid and Medicare Part B patients to use their drugs. Such patients include a large population with chronic illnesses. However, there are challenges associated with accurately tracking and reporting 340B discounts, and manufacturers are concerned that payors will use 340B discounts on patients who have already benefited from another price concession on the same drug.

One way this can occur is through a duplicate discount. The manufacturer sells drugs to a covered entity at the 340B price and later pays a Medicaid rebate on the same drug. While HRSA prohibits this type of duplicate discount, identifying and preventing it from occurring can be challenging due to poor coordination among covered entities, contract pharmacies, and state Medicaid agencies.

Multiple price concessions can also occur through a "stacked" discount. The manufacturer provides a 340B discount on a commercial claim that also received a rebate negotiated between a pharmacy benefit manager (PBM) and a manufacturer. Although not explicitly prohibited, stacked discounts could violate agreements between PBMs and the manufacturers. They can occur if the patient is privately insured and qualifies as an "eligible patient" as defined by HRSA.

In addition to duplicate and stacked discounts, manufacturers are concerned about drug diversion. Diversion occurs when a 340B discount is used on a patient who does not meet HRSA's definition of an eligible patient. Drugs dispensed through contract pharmacies are particularly susceptible to diversion, as pharmacists are often unaware whether a patient's prescription qualified for 340B.

Several legal challenges stem from manufacturers' concerns over duplicate discounts, stacked discounts, and diversion. Beginning in 2021, drug manufacturers filed six lawsuits that challenged HRSA's authority to issue warnings and fees in response to the manufacturers' decision to restrict the availability of 340B discounts for drugs dispensed through contract pharmacies. In these lawsuits, manufacturers claim that the expansion of contract pharmacies has increased duplicate discounts. The trial courts sided with HRSA in four of these disputes and with manufacturers in two. Several appeals are ongoing as a result of these rulings. The Third Circuit Court of Appeals recently sided with manufacturers in one of these appeals.

A recent decision in the U.S. District Court of South Carolina has called into question HRSA's authority to enforce a patient definition that is more restrictive than that described in 340B's enabling legislation. This definition requires a covered entity to initiate the services resulting in the relevant prescription. The court's decision—while consistent with the Third Circuit ruling that HRSA has overreached at times in its regulation of the 340B program—considers the initiation of services irrelevant and takes a broader view of who may be considered a patient. As a result, this decision may increase discounts available for prescriptions previously flagged as diversion (i.e., a primary care covered entity whose patient receives cancer treatment from a different healthcare facility may now be able to use 340B discounts on that patient's cancer drugs). Notably, several drug manufacturers filed amicus briefs supporting HRSA's ability to limit 340B discounts on these prescriptions in the South Carolina case. Given these recent decisions, litigation will likely continue to challenge other 340B policies and guidelines that HRSA has implemented, rather than being directly legislated by Congress.

To track and reduce the incidence of stacked discounts, and as a condition to receive discounts, manufacturers have required many covered entities to submit prescription claims data for drugs dispensed through contract pharmacies through a third-party contractor called 340B ESP. The 340B ESP platform is not without its own controversy, however, as covered entities have expressed concerns over reporting requirements and delays in restoring 340B discounts.

Even as pharmaceutical manufacturers take steps to reduce the incidence of diversion, duplicate discounts, and stacked discounts, whether such efforts will be fruitful and how they will affect the size of the 340B program remains to be seen.

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