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, but 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 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.

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IQVIA Research Summary

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

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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.

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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.

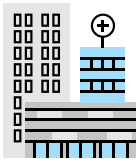
For-profit companies and large consolidated hospital systems benefit more from 340B than patients.

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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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.

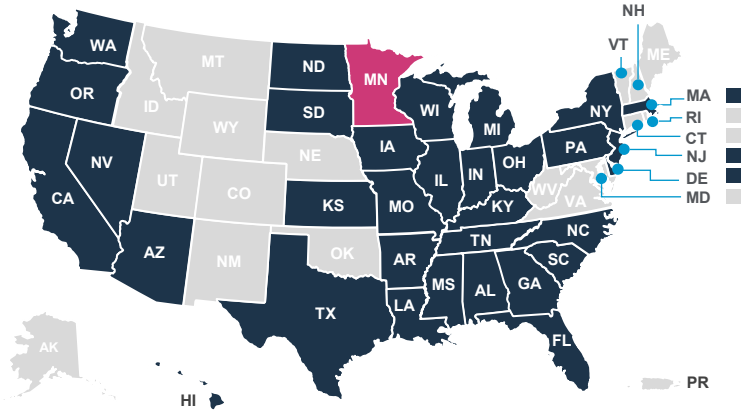
Fast Facts: 340B Nationwide

- 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

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.

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