

Opposition to Minnesota 340B legislation



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.

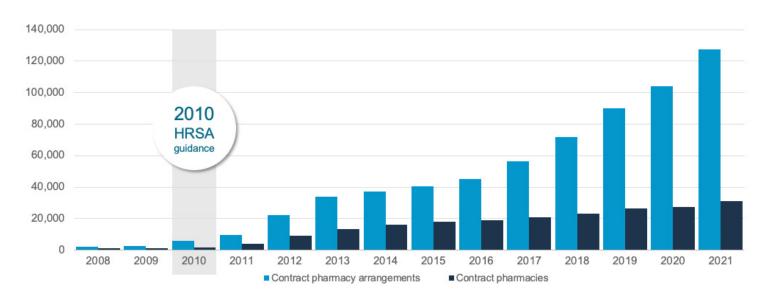


Learn more at PhRMA.org/340B

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.



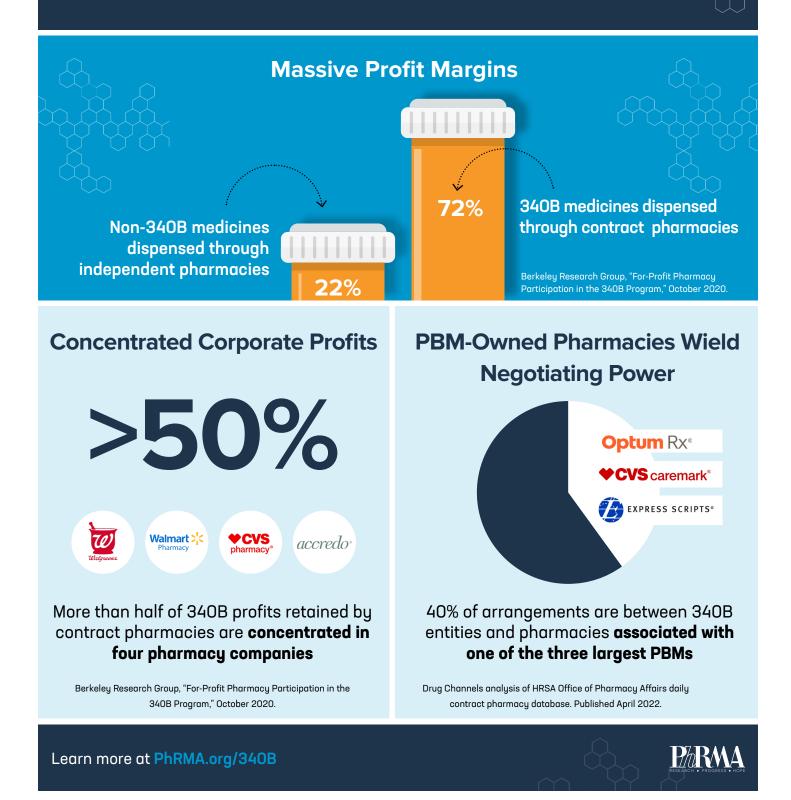
340B Hospital Contract Pharmacies and Pharmacy Arrangements*

*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.



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

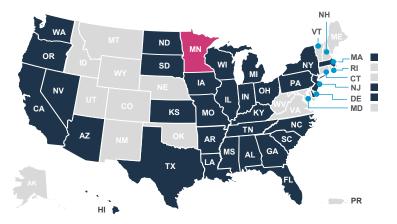
- 57% of all hospitals in the United States participate in the 340B program.
- Discounted 340B purchases reached nearly \$54 billion in 2022 nationwide – 23% higher than in 2021.
- The number of contract pharmacies has grown nationwide by more than 8,000% since 2010.
- 46% of contract pharmacy arrangements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

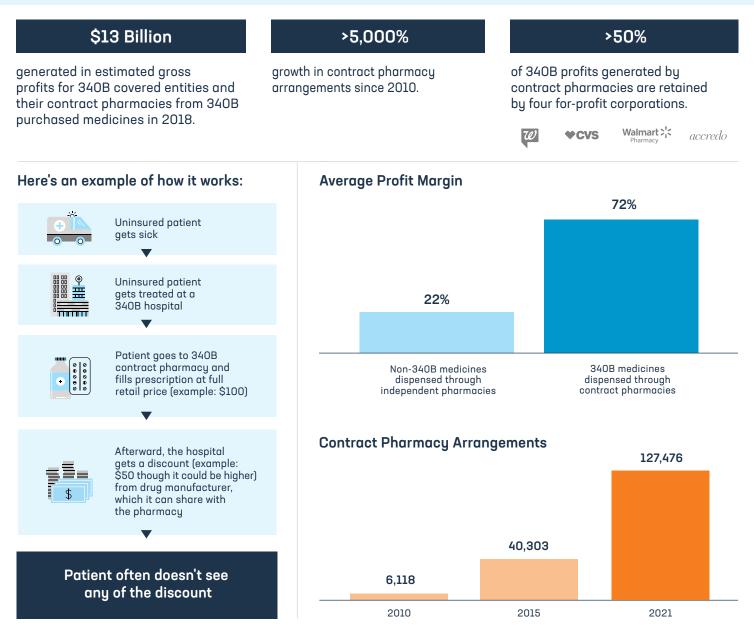
- Charitable care is the free or reducedcost care provided to qualifying patients.
- Unfortunately, 77% of nonprofit hospitals nationwide spent less on charity care than they gained from tax breaks.
 - The top performing 340B hospitals nationwide collected nearly \$10 in total profit for every \$1 they 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.



Learn more at PhRMA.org/340B

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.



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





In Opposition to Minnesota House File 4991 / Senate File 5159 <u>340B Contract Pharmacy Mandate</u> March 2024

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes Minnesota House File 4991 (HF 4991) / Senate File 5159 (SF 5149). HF 4991 / SF 5159 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.

HF 4991 / SF 5159 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 HF 4991 that have serious constitutional defects and are being challenged in federal court.

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

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 pharmacy₁

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.

HF 4991 / SF 5159 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.² 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.³ 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.⁴

PhRMA respectfully opposes the provisions outlined above and appreciates your consideration prior to advancing HF 4991 / SF 5159.

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 Conti, Rena M., and Peter B. Bach. "Cost consequences of the 340B drug discount program." Jama 309.19 (2013): 1995-1996.

³ Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," GAO-18-480, June 2018.

⁴ Berkeley Research Group. For-Profit Pharmacy Participation in the 340B Program. October 2020.