DRUGMAKERS PULLING $8 BILLION OUT OF SAFETY-NET HOSPITALS

MORE EXPECTED AS GROWING NUMBER IMPOSE OR TIGHTEN 340B RESTRICTIONS

EXECUTIVE SUMMARY

As of June 1, 2023, a total of 21 drugmakers have imposed restrictions on community and specialty pharmacies with which 340B hospitals contract to dispense 340B drugs to eligible patients, and many of these have significantly tightened the restrictions since March 2023. More have announced restrictions since this analysis was completed. These restrictions allow drugmakers to profit from avoiding 340B program penalties on excessive price increases and high-dollar discounts on pricey specialty drugs. Both the Trump and Biden administrations found that these actions violate the law, but manufacturers have argued in federal court that the statute is unclear, with some courts agreeing and others not. Litigation is ongoing. These restrictions harm patients as well as strip rural and safety-net hospitals of significant financial support at a time when these hospitals are still reeling from the pandemic and face severe labor shortages.

New data on 340B sales for 2020 and 2021 obtained from the Health Resources & Services Administration (HRSA) through a Freedom of Information Act (FOIA) request combined with member data on 340B savings at the national drug code (NDC) level has allowed 340B Health to estimate the total 340B savings associated with community and specialty pharmacies for the first 21 manufacturers in 2023 dollars as well as analyze specific patterns of manufacturer behavior.

Findings:

- **$8.4 billion at stake for the hospital safety-net.** The 21 manufacturers imposing restrictions as of June 1, 2023, account for $8.4 billion in annual 340B savings from community and specialty pharmacy relationships. As manufacturers push the envelope on restrictions as far as they legally can—and sometimes further—virtually no contract pharmacy savings will remain.
- **If not stopped, a rapid loss of this magnitude would be catastrophic for the health care safety net and the patients it serves.** 340B hospitals have been forced to cut programs and services, and patients are unable to receive discounted drugs at contract pharmacies.
- **Billions more at risk.** If all manufacturers follow the lead of these 21, safety-net hospitals could see billions more in reduced safety-net funding very quickly.
- **Restrictions will lead to higher drug prices.** $4.6 billion of the lost savings come from manufacturers using restrictions to avoid steep penalties for excessive price increases they have imposed. Researchers estimate that lower price increases prompted by 340B inflation penalties reduced Medicare Part D pharmacy expenditures by $7 billion between 2013 and 2017.

- **Restrictions severely limit 340B access to discounts on expensive specialty drugs used by hospital patients, undermining the purpose of 340B and stripping the safety net of resources.** Specialty drugs account for $5.3 billion of contract pharmacy savings on restricted drugs due to their high prices and the penalty for price increases. Overall, just 15 of the 500 restricted drugs account for more than half of the associated contract pharmacy savings, and nine of these are specialty drugs. Due to the special handling, patient support, and other requirements for some of these drugs, very few hospitals operate the specialty pharmacies that dispense them and have relied on contract pharmacy arrangements to purchase them at the 340B discount. Restricted access to these drugs dramatically shrinks 340B, as these drugs have taken up a growing share of the prescription drug market, rising from virtually none when 340B was enacted in 1992, to 27% in 2010, to a whopping 52% today. These actions sap safety-net resources as well as limit the ability of hospitals to make these drugs affordable for the patients who need them.

INTRODUCTION

The 340B drug pricing program, established in 1992, requires drug companies to provide outpatient drugs to eligible health care organizations (covered entities) at reduced prices. In return, these companies receive coverage for their drugs under Medicare Part B and Medicaid. Covered entities under 340B include providers that are critical to treating low-income and rural populations. These include certain public and nonprofit hospitals, federally qualified health centers, Ryan White HIV/AIDS clinics, family planning clinics, hemophilia treatment centers, and others. Congress established 340B to enable these providers to purchase outpatient drugs at a reduced cost and to use savings "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] 340B provides resources for these safety-net organizations at no cost to taxpayers, as drugmakers provide the discounts and providers invest the savings from the discounts into patient care.

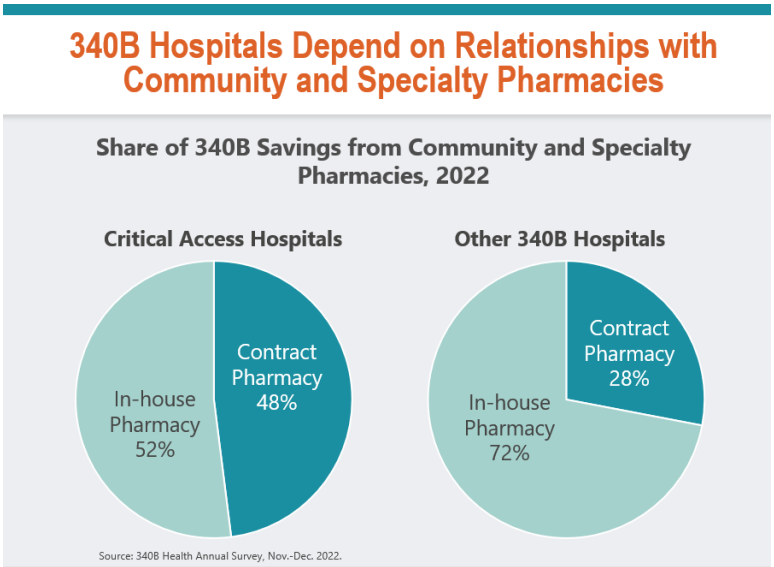
340B provides resources for the safety net at no cost to taxpayers.

340B providers receive discounts for drugs dispensed to eligible patients by the covered entity as well as for those dispensed to their patients by community and specialty pharmacies with which they contract. As an integral part of 340B, contract pharmacy relationships enable better patient access to prescribed medications, and 340B savings on these drugs provide critical funding for safety-net providers.[2] More than half of 340B hospitals report they do not operate in-house retail pharmacies, and only one in five have their own specialty pharmacies.[3] Hospitals report that 340B savings from community and specialty pharmacy relationships account for half the total savings for critical access hospitals (CAHs) and about a quarter for other 340B hospitals.[4]

Since July 2020, a growing number of drug companies have imposed limits on 340B discounts on outpatient prescription drugs sold to safety-net hospitals and dispensed to eligible patients through community and specialty pharmacies under contract with 340B hospitals and, in some cases, grantees. The federal government has taken the position that such actions violate the law, but the number of

More than half of 340B hospitals report they do not operate in-house retail pharmacies, and only one in five have their own specialty pharmacies.

companies imposing restrictions has continued to grow even as the government has issued enforcement letters against multiple drug companies. Manufacturers have argued in federal court that the statute is unclear, with some courts agreeing and others not. Litigation is ongoing.



Numerous reports have documented the harm of these restrictions to hospitals and the patients they serve.[5,6] These restrictions are part of longstanding efforts by the pharmaceutical industry to cut back on its support for the health care safety net and avoid penalties for repeatedly raising prices at rates greater than inflation as well as high-dollar discounts on pricey specialty drugs.[7]

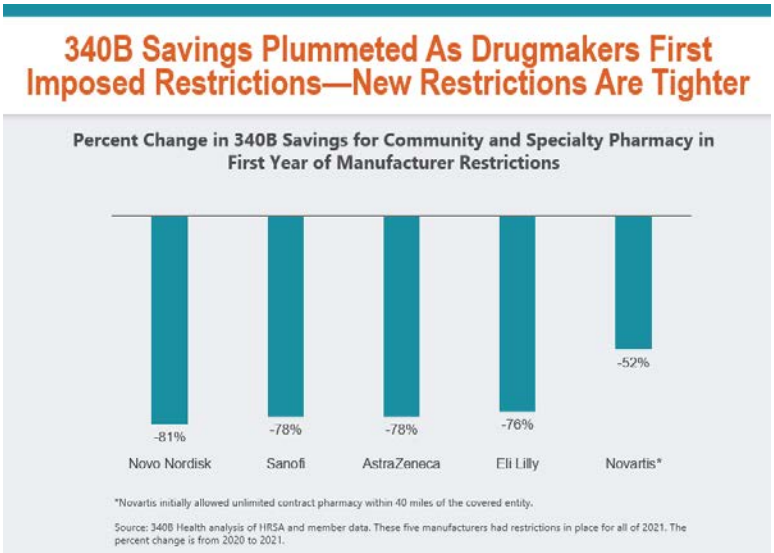
This report couples new data from HRSA on the volume of 340B purchases through contract pharmacy with data collected from 340B Health members to estimate the actual change in 340B savings associated with the first five manufacturers to impose restrictions as well as to calculate the contract pharmacy savings associated with all 21 manufacturers who had imposed restrictions as of June 1, 2023. We also look at patterns in the types of drugs that have been restricted and what that means for 340B hospitals, their patients, and the market for drugs overall. Prior analyses were based on overall sales volume from HRSA.[8] The new data from HRSA allow us to look specifically at contract pharmacy for the first time. A more detailed methodology can be found in Appendix 1.

FINDINGS

Even With Less Stringent Restrictions at the Outset, Contract Pharmacy Savings Declined by 70%

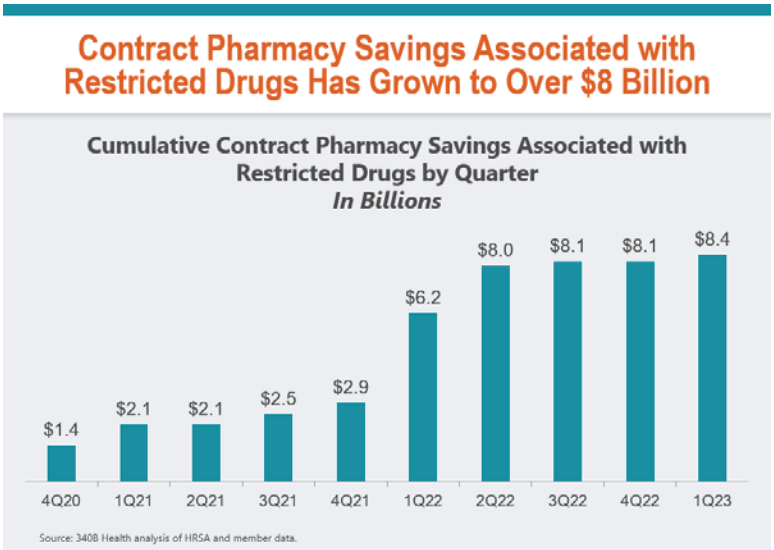
The most recent data on the volume of 340B purchases available from HRSA are for 2021. These data allow 340B Health to estimate the impact of the restrictions on contract pharmacy for the five manufacturers that had contract pharmacy restrictions in place for all of 2021. These were AstraZeneca, Eli Lilly, Novartis, Novo Nordisk, and Sanofi. In 2021, the restrictions of these manufacturers were significantly less stringent than those imposed by many manufacturers today. Most allowed for unlimited contract pharmacy with data submission, exceptions for system-owned pharmacies, and except for one, no limit on how far away a contract pharmacy could be from the 340B covered entity. The experience with these manufacturers provides a window into the level of savings that may have been lost as more manufacturers have imposed restrictions and these restrictions have intensified. From 2020 to 2021, our analysis found contract pharmacy savings declined by $1.5 billion, or 70%, for the five manufacturers that had restrictions in place for all of 2021. Novartis was an outlier at only a 52% reduction. Novartis's restrictions were different at that time in that they allowed unlimited contract pharmacies within a 40-mile radius with no data submission. Without Novartis the average level of savings approached 80%. This figure is understated because some of these five manufacturers implemented restrictions in the latter part of 2020.

The 70% reduction reflects a period when few hospitals were submitting data. In a 340B Health survey conducted at the end of 2021, only 4% of respondents reported providing claims data in exchange for unlimited access to contract pharmacy.[9] By the end of 2022, this percentage had increased to 42%.[10] While data submission likely mitigated the impact of restrictions in 2022, this option is now being withdrawn by a growing number of manufacturers. Prior to 2023, most manufacturers were allowing exceptions for system-owned contract pharmacies, which nearly half of 340B hospitals use.[11] Many have now eliminated this exception.



$8.4 Billion in Annual Contract Savings Is Associated With 21 Drugmakers With Restrictions in Place—The Majority Is Gone and Nearly All Is Expected To Be Lost as Restrictions Tighten

As of June 1, 2023, a total of 21 manufacturers had imposed restrictions on contract pharmacy, covering 1,822 NDCs and more than 500 drugs.[a] Using the baseline volume of drugs purchased through 340B by hospitals in 2020 and 2023 pricing, analysis found restricted drugs account for $8.4 billion in 340B savings for purchases through entities registered as contract pharmacies. Contract pharmacies include both pharmacy companies as well as pharmacies wholly owned by the systems of which many 340B hospitals are a part. More manufacturers have announced restrictions since then, and it is possible all manufacturers will impose such restrictions if court decisions allow it.



The experience with these new, tighter restrictions suggests that far more than 70% of the contract pharmacy savings will be lost. For manufacturers with the tightest restrictions, hospitals with any in-house pharmacies capable

[a] An NDC, or national drug code, is a unique number that identifies for each product the labeler (manufacturer, repackager, or distributor), the drug, strength, dosage form, formulation, and package size and types. In this report, the word "drug" refers to all the NDCs for one manufacturer associated with a particular compound or biologic agent.

of dispensing 340B drugs to patients will not be allowed any contract pharmacies. These hospitals will lose all the savings associated with contract pharmacy. The tightest restrictions will allow a single contract pharmacy for hospitals that do not have their own pharmacy, but it must be within 40 miles. There is no exception for system-owned contract pharmacies, though they can be chosen as the one contract pharmacy. Some manufacturers only allow one contract pharmacy even if it means that hospitals must choose between a specialty and a retail pharmacy and may lose access to 340B discounts for some drugs as a result. The importance of specialty pharmacies is discussed in detail below. All these scenarios result in most contract pharmacy savings going away.

$8 billion or more at stake for the hospital safety net

If Not Stopped, a Rapid Reduction in Safety-Net Resources of This Magnitude Would Be Catastrophic for the Health Care Safety Net

This cut is occurring rapidly, giving safety-net providers little time to prepare. 340B hospitals are the backbone of the nation's health care safety net. 340B disproportionate share (DSH) hospitals, a mix of larger urban and rural hospitals, provide 77% of the hospital care provided to Medicaid patients and 67% of all hospital unpaid care while having extremely tight operating margins.[12,13] Three-quarters of CAHs, which are small, predominantly rural hospitals, depend on 340B savings to keep their doors open.[14] For all types of hospitals, 340B supports a wide range of programs and services targeted to meet the health and social needs of underserved populations as well as the broader community, many of which would not otherwise be financially sustainable.[15,16]

The contract pharmacy restrictions already are taking a toll. A 340B Health survey conducted at the end of 2022 finds safety-net hospitals have begun cutting programs and services. Hospitals reported patients receiving discounted drugs at contract pharmacies are experiencing harm when the inability to access critical medications at an affordable price leads to skipped doses, worsening health status, and emergency visits or hospital admissions.[17] At the time of the survey, hospitals expected these impacts to intensify if these restrictions became more stringent or more widespread.[18] Both have occurred.

These cuts put at risk programs that increase access to care for underserved populations in both urban and rural areas. Many 340B-supported services improve patient outcomes such as increased medication adherence, reduced readmission and emergency department visit rates, and lower A1C levels for diabetes, among others.[19]

Cuts to contract pharmacy have led to service reductions and patient harm.

Services that would operate at a loss without subsidies from 340B are particularly at risk. Examples include trauma, burn units, behavioral health, and obstetrics.[20] One hospital reported closing outpatient behavioral health services, another cut funding for 19 school-based clinics, and another closed a rural health clinic.[21] A health system with the only trauma unit in a multi-state area noted the importance of 340B savings to maintaining this critical but money-losing service.[22]

If Restrictions Spread Across All Manufacturers, the Annual Hit to the Hospital Safety Net Could Be Billions More

The 21 manufacturers that have imposed restrictions as of June 1, 2023, account for a significant share but not all contract pharmacy savings.[23] More have imposed restrictions since. If all manufacturers were to impose restrictions, the impact could be billions more.

Restrictions Shield Manufacturers From the Consequences of Pricing Behavior

Analysis of the specific drugs targeted by restrictions and their associated level of 340B savings shows that manufacturers are targeting high-priced specialty drugs and drugs that have discounts substantially more than the basic discount of 23.1% because of penalties imposed for excessive price increases. These drugs drive prescription drug spending and 340B program size.

Drug Company Actions Skirt Penalties Intended To Restrain Price Increases, Leading To Higher Prices for All

The basic discount in 340B is 23.1% for branded drugs, but manufacturers face penalties for price increases in excess of inflation. Repeated, excessive price increases can result in penalties that push the 340B price to as little as one penny or a discount of nearly 100%. We characterize a price as "nominal" if the discount has risen to 85% or more, a level nearly four times the basic discount.

Penalties for excessive price increases can quadruple the basic 340B discount.

Research has shown the 340B inflation penalty serves as a restraint on the drug company pricing decisions that affect all purchasers. A study of 606 brand-name drugs used by Medicare beneficiaries between 2013 and 2017 found increases in the percentage of drug sales subject to inflation penalties were associated with lower drug price increases. Researchers estimated that lower price increases to avoid the 340B penalty reduced Medicare Part D pharmacy expenditures by $7 billion over the period.[24]

Skirting these penalties removes an important constraint on price increases. $4.6 billion of the contract pharmacy savings on restricted drugs is accounted for by nominally priced drugs.[b] For seven of the 21 manufacturers, these drugs make up more than three-quarters of the savings associated with restricted drugs dispensed through contract pharmacy.

Restrictions Enable Drugmakers To Avoid Discounts on the Most-Costly Drugs

While manufacturers are restricting contract pharmacy for a broad range of drugs, restrictions have a disproportionate impact on access to 340B pricing for specialty drugs. Payers and manufacturers classify certain drugs as "specialty" because of their handling requirements, need for patient monitoring and support, data-collection requirements, and/or high price. These drugs are used to treat chronic, serious, or life-threatening conditions such as cancer, rheumatoid arthritis, growth hormone deficiency, and multiple sclerosis. As such, many of these drugs must be dispensed by a specialty pharmacy with the unique capabilities to handle a particular drug and provide appropriate physician and patient supports.

[b] A drug can be both specialty and nominally priced.

Specialty drugs are rapidly overtaking the pharmaceutical market. At the program's inception in 1992, there were virtually no specialty drugs. They have grown rapidly to 27% of pharmaceutical spending in 2010 to a whopping 52% in 2021.[25,26] This trend is an important driver of prescription drug spending overall as well as 340B program size.

Costly specialty drugs represent an outsized share of contract pharmacy savings for restricted drugs.

The tens of thousands of retail pharmacies where people most commonly pick up their prescriptions are rarely accredited specialty pharmacies. Specialty pharmacies are typically mail-order, far fewer in number, and not even available in most communities. In fact, only 1,570 pharmacy locations, about 2% of the total number of pharmacies, had specialty accreditation in 2021.[27] This includes pharmacies owned and operated by 340B covered entities.

340B Health survey data have found that only one in five 340B hospitals have in-house specialty pharmacies, and the vast majority rely on contracts with either a specialty pharmacy company or a system-owned specialty pharmacy.[28] Specialty pharmacy companies often centralize the dispensing of drugs for a particular disease state to ensure the clinical expertise to support patients and physicians is available in one place. As a result, 340B discounts on these pricey drugs in many cases only are accessible through multiple contracts with specialty pharmacies, many of which will be more than 40 miles away from the hospital.[29] For similar reasons, health care systems often centralize specialty pharmacy operations, also leading to issues with distance requirements.

The high prices for these drugs result in high-dollar discounts on 340B purchases. Of the contract pharmacy savings for the 21 manufacturers that had restrictions in place as of June 1, 2023, $5.3 billion is associated with specialty drugs.[30] For 11 of the 21 drug companies that have imposed restrictions, more than 75% of the contract pharmacy savings come from specialty drugs. 340B savings on these very high-cost drugs fund important services and supports that increase medication adherence and improve patient outcomes.[31,32,33] Limiting contract pharmacy allows manufacturers to increase profits on these drugs at the expense of the health care safety net.

Restrictions on Specialty Drugs Have an Outsized Impact on 340B Savings—Even More So When They Come With High Penalties

Just 15 of the more than 500 restricted drugs account for half of the associated contract pharmacy savings. All 15 are either specialty or highly discounted and many are both. All but one of these drugs have formulations with discounts greater than 50%—double the basic discount of 23.1%. Of the nine specialty drugs on this list, five are nominally priced. Of the six that are not specialty, four are nominally priced.

Specific blockbuster drugs among these 15, such as AbbVie's *Humira* and Amgen's *Enbrel*, have been singled out for having excessive price increases unsupported by new clinical evidence.[34] These are among those that are both nominally priced and specialty.

This level of concentration illustrates the impact of manufacturer pricing decisions—both high prices and excessive price increases—on program size. Avoiding 340B discounts not only removes constraints on price increases but also impacts a critical source of affordable drugs. New research finds that launch prices for new drugs have been increasing at 20% per year since 2008, an unsustainable trend that makes 340B discounts more important than ever.[35]

***Humira:* Excessive Price Increases Yield Large 340B Discounts**

Humira is used to treat many inflammatory conditions in adults including rheumatoid arthritis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. The GoodRx price for one patient for one year is nearly $80,000 and the list price is even higher.[36] At this price, *Humira* is classified as a specialty drug by all four of the largest specialty pharmacy companies and their vertically integrated PBMs.[37] In 2022, sales of *Humira* totaled $21.2 billion, making it the world's second-top-selling drug behind the dominant COVID vaccine.[38] AbbVie has faced sharp criticism for repeatedly raising the price of *Humira* with no supporting evidence of improved clinical benefit.[39] As a result of those pricing decisions, several of its formulations are penny-priced when sold to 340B covered entities. Total 340B savings for *Humira* across contract and non-contract pharmacy approached $3 billion for hospitals in 2021, the year before AbbVie imposed restrictions. Several biosimilars have now been introduced.

Restrictive Policies Are Designed To Maximize the Impact on Specialty Drugs, Undermining Program Intent and Stripping Resources From the Health Care Safety Net

Because of the limited number of specialty pharmacies and the fact that the vast majority of 340B hospitals rely on contract specialty pharmacies or pharmacies owned by their parent systems to access 340B savings for these drugs, policies common to multiple manufacturers have an outsized impact on specialty drugs. These include:

- **Limiting an organization to no contract pharmacy if they have their own retail pharmacy.** Retail pharmacies are more commonly owned by 340B hospitals than specialty pharmacies as they require less scale to operate efficiently. But for several manufacturers, owning a retail pharmacy means the hospitals cannot contract with even one specialty pharmacy.
- **Allowing only one retail or specialty contract pharmacy if a hospital has no pharmacy of their own**. Specialty and retail pharmacies typically do not dispense the same drugs, leaving hospitals with difficult choices. A recent member survey found that 51% of 340B hospitals, excluding CAHs, have neither an in-house specialty pharmacy nor an in-house retail pharmacy.[40] Additionally, not every specialty pharmacy location for any given company maintains the capacity to handle each drug, leaving hospitals having to choose among disease states. Because of special requirements unique to a given drug or class of drugs, dispensing of certain drugs is often centralized at a particular pharmacy location that may be hundreds or even thousands of miles away from any given hospital. Using Johnson & Johnson (J&J) as an example, Accredo, a major specialty pharmacy company, has 16 Therapeutic Resource Centers including specific centers specializing in diseases treated by different J&J products, including oncology, HIV, and inflammatory conditions.[41]
- **Placing distance restrictions on where a contract pharmacy is located relative to the hospital.** A 40-mile distance limitation on contract pharmacy is not reasonable when considering specialty drugs. In a recent survey, 86% of 340B hospitals reported that most of their contracted specialty pharmacies are outside of a 40-mile radius.[42]
- **Eliminating the exception for system-owned pharmacies.** Many individual hospitals do not have the resources or scale to operate their own specialty pharmacies. Centralizing the dispensing of specialty drugs in one or more mail-order, system-owned pharmacies ensures

scale in purchasing as well as the efficient provision of the clinical expertise to support patients and physicians. Taking away this option dramatically reduces access to 340B pricing for specialty drugs. Also, some larger systems have wholly owned specialty pharmacies that serve system hospitals outside a 40-mile radius, leaving these hospitals to seek access through private, for-profit specialty pharmacies and pay their fees.[43] Note that hospitals can choose a system-owned pharmacy as their one exception.

CONCLUSION

Restrictions on relationships with community and specialty pharmacies with which 340B hospitals contract to access savings on drugs represent a significant and immediate threat to the nation's health care safety net. 340B hospitals not only provide the lion's share of Medicaid services to hospital patients and unpaid hospital care, they also use 340B savings to invest in a vast range of programs and services that expand access to care, improve patient outcomes, and support critical clinical services that could not be sustained on their own. A cut of $8 billion or more to 340B safety-net funding puts all these benefits at risk, benefits that come at no cost to taxpayers.

APPENDIX 1: METHODOLOGY

340B Health obtained 340B sales volume by NDC for 2020 and 2021 for contract pharmacies and for the program in total from HRSA via two FOIA requests. 2020 represents a baseline period during which no manufacturers had restrictions in place for the entire year. During 2021, five manufacturers had imposed restrictions for the entire year.

To estimate the current value of the 340B savings associated with restricted drugs, 340B Health obtained 2023 data on the difference between purchasing outside the program at a group purchasing organization (GPO) price relative to purchasing at the 340B price for each NDC. These data were combined with the volume data from HRSA to estimate the actual change in savings over time as well as to project what the impact could be going forward. Using savings data from 2023 isolates changes that are due to volume and provides a current estimate of the financial impact of any volume changes. The savings figures do not account for any fees paid to contract pharmacies.

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340B HEALTH REPORT:

Drug Company 340B Restrictions Are Stripping Billions of Dollars from the Health Care Safety Net

The Initial Losses of 340B Savings Are Just the Tip of the Iceberg

$1.1 billion

The amount hospitals lost in 340B savings from just five companies in 2021 alone

AstraZeneca, Eli Lilly, Novartis, Novo Nordisk, and Sanofi sell only 22% of drugs affected today

Estimated annual losses of 340B savings are **in the billions**

Lost 340B Savings Are Hurting Safety-Net Hospital Patients

1 in 3
critical access hospitals have been forced to cut services due to restrictions

2 in 3
hospitals with impacted discounted drug assistance programs report patient harm

90%
of hospitals expect to cut services if restrictions persist

Targeted Drugs Maximize Losses to Safety-Net Hospitals and Profits to Drug Companies

Drug companies design restrictions to...

- **Skirt penalties** for price hikes to avoid 340B discounts up to 85%+
- **Avoid big-dollar discounts** on specialty drugs that make up >50% of Rx spending

340BHEALTH

READ THE FULL REPORT:
www.340bhealth.org/march2023report

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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.

Interviewee

Sayeh Nikpay
Associate Professor, Division of Health Policy & Management, School of Public Health, University of Minnesota

Opposition to Minnesota 340B legislation

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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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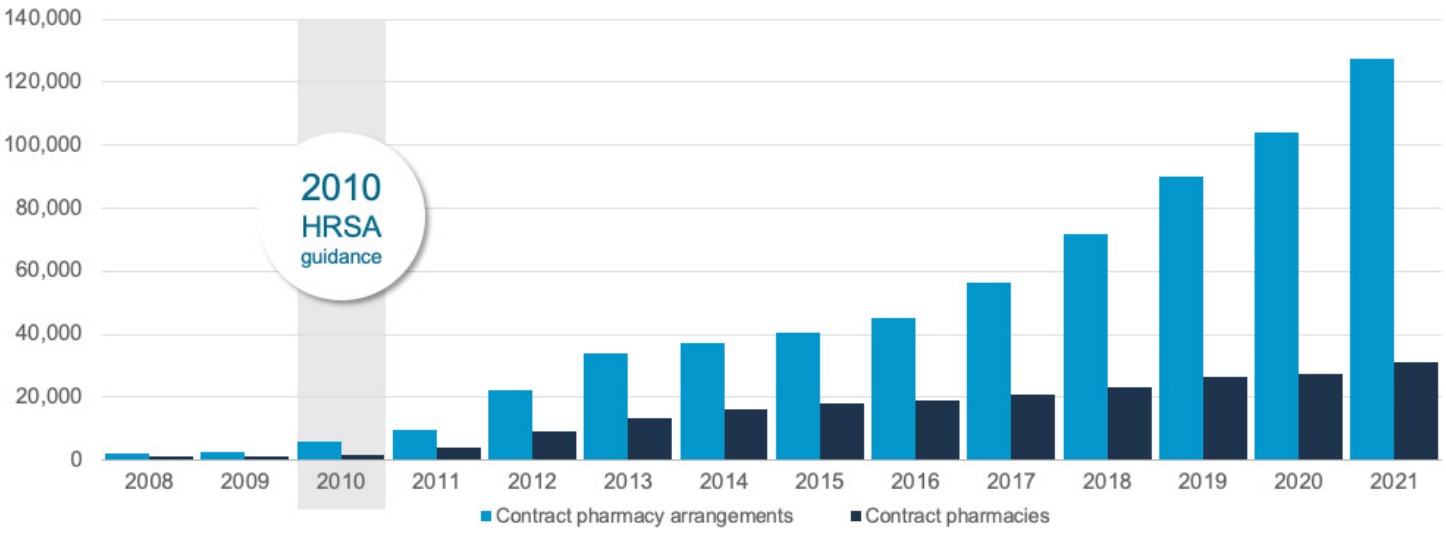
340B Contract Pharmacy Participation Has Increased Dramatically

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.

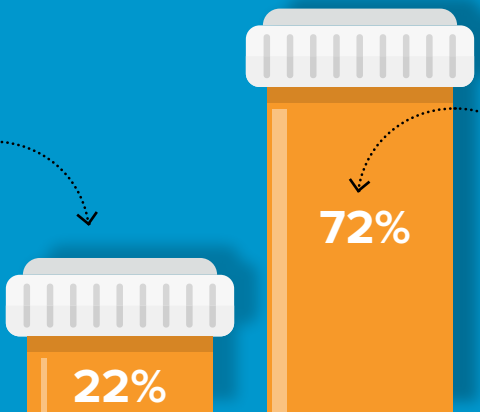
Learn more at PhRMA.org/340B

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.

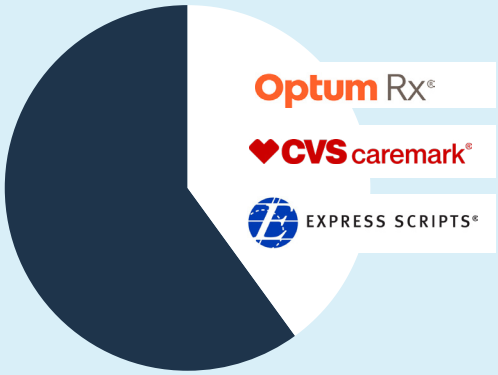
Concentrated Corporate Profits

>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.

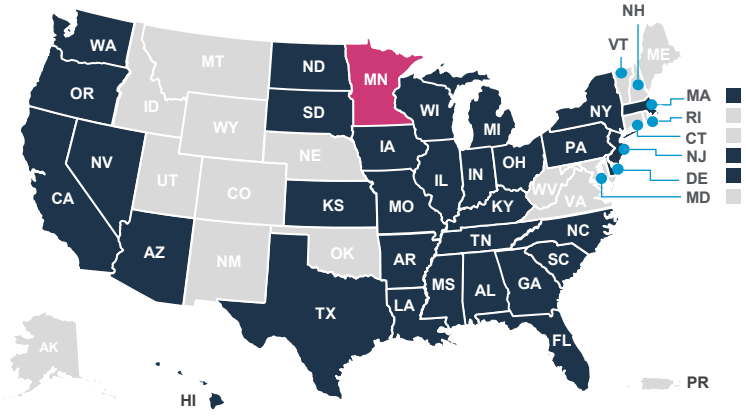
Fast Facts: 340B Nationwide

- 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%

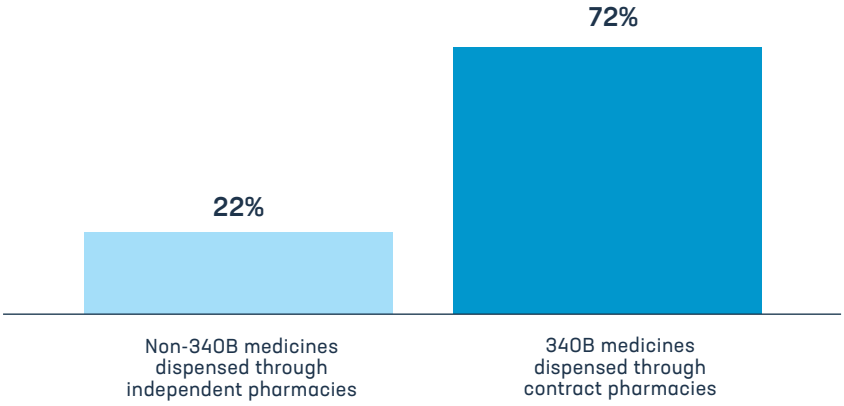
of 340B profits generated by contract pharmacies are retained by four for-profit corporations.

Here's an example of how it works:

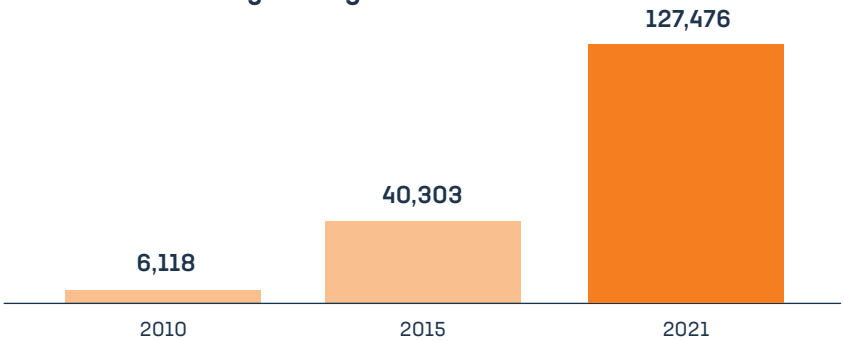
- Uninsured patient gets sick
- Uninsured patient gets treated at a 340B hospital
- Patient goes to 340B contract pharmacy and fills prescription at full retail price (example: $100)
- Afterward, the hospital gets a discount (example: $50 though it could be higher) from drug manufacturer, which it can 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 File 4991
340B Contract Pharmacy Mandate
March 2024

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

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.

HF 4991 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.

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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] 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.

MINNESOTA 340B HOSPITALS SERVE MORE PATIENTS WITH LOW INCOMES, WHO LIVE WITH DISABILITIES, AND/OR IDENTIFY AS BLACK

FACTS ON PATIENTS OF 340B HOSPITALS IN MINNESOTA

Analysis of Medicare claims and cost report data in Minnesota finds:

- Relative to non-340B hospitals, patients of 340B hospitals are:
  - 101% more likely to be dually eligible for Medicaid and Medicare (a proxy for having low-income),
  - 66% more likely to be originally eligible for Medicare because of a disability making them more costly to treat, and
  - 225% more likely to be persons identifying as Black/African American.
- Medicaid makes up a 68% higher share of operating revenue for 340B DSH hospitals.
- 340B hospitals provide 88% of all hospital care provided to Medicaid patients in Minnesota.

Introduction

The 340B Drug Pricing Program was created to enable participating entities to stretch scarce resources to reach more eligible patients and provide more comprehensive services by allowing these entities to obtain covered outpatient drugs at reduced prices. Prior research has documented that 340B supports hospitals with certain safety-net characteristics, such as those serving a higher share of patients with Medicaid and/or experiencing low-income.[1]

To better understand patterns of care provided by hospitals in 340B, 340B Health contracted with L&M Policy Research to examine differences in sociodemographic and health-associated Medicare enrollment characteristics between patients of 340B and non-340B hospitals in 2019, updating results from an earlier study based on 2016 information.[2] Specifically, this study compares characteristics of Medicare fee-for-service beneficiaries who received separately-payable Part B discount-eligible drugs at 340B disproportionate share hospitals (DSH) and non-340B acute care hospitals to assess whether 340B hospitals serve proportionally more historically underserved populations. Within the Medicare program, patients who are dually eligible for Medicare and Medicaid, a proxy for having low income, and/or are eligible for the program based on a disability tend to be more complex and costly to treat.[3] People who identify as being of Black/African American ancestry have higher prevalence of some chronic conditions, such as hypertension[4] and diabetes,[5] and utilization patterns indicative of less access to primary and preventive care[6] than White beneficiaries due to structural racism and other historical inequities.[7]

Additionally, prior research at the national level has shown that 340B DSH hospitals provide the majority of all hospital care provided to Medicaid patients,[8] but no similar analysis existed at the state level. Medicaid payments do not typically cover the cost of care, with hospitals receiving direct payments of 84 cents for every dollar spent providing care to Medicaid patients.[9] 340B Health commissioned Dobson DaVanzo & Associates to perform a state-level analysis comparing DSH hospitals participating in the 340B program to non-participating acute care hospitals in the delivery of services to Medicaid patients.

Methodology in Brief

The research teams at L&M Policy Research and Dobson|DaVanzo used the Medicare Inpatient Prospective Payment System (IPPS) final rule and correction notice impact files to identify the universe of eligible hospitals to include in the study. The team then used the HRSA Office of Pharmacy Affairs

Information System (OPAIS) Covered Entity Daily Report to identify 340B participation status in the appropriate year to divide these hospitals into two groups: (1) those participating in the 340B program and (2) all other IPPS acute care hospitals.

To identify 340B discount-eligible drugs, which are billed and paid outside of Medicare's outpatient prospective payment system's (OPPS) bundled payments (referred to here as "separately-payable Part B drugs"), L&M Policy Research selected HCPCS codes from outpatient Medicare claims for 2019 with a revenue status code of "G" (drug/biological pass-through) or "K" (non-pass-through drug/biological, radiopharmaceutical agent, certain brachytherapy sources).

L&M Policy Research identified the population of Medicare beneficiaries with claims for any separately-payable Part B drugs any point in calendar year 2019. They identified the setting where these patients received their drugs, and anyone who received Part B drugs in more than one type of location was omitted from their population (approximately 3% of study patients nationally).

Finally, L&M Policy Research used the Medicare Beneficiary Summary Files (MBSF) to connect the identified patient populations with relevant demographic and enrollment information, such as reason for Medicare entitlement, dual-eligibility status, and race/ethnicity.

Using Medicare hospital cost reports for FY 2018, Dobson|DaVanzo obtained Medicaid revenue as a percent of hospital operating revenue and the percentage of all Medicaid hospital care provided by 340B hospitals measured as net Medicaid revenue for 340B hospitals divided by total Medicaid revenue for all hospitals in the state.

Results

In 2019, relative to non-340B hospitals, 340B DSH hospitals in Minnesota delivered a higher proportion of their services to Medicare patients who are experiencing low income and/or were originally eligible for Medicare because of a disability. They also delivered a higher proportion of care to those identifying as Black/African American. In FY 2018, Medicaid made up a greater share of operating revenue for 340B hospitals than non-340B hospitals. In fact, 340B hospitals provide 88% of all Medicaid hospital care in Minnesota. Comparative values for 340B DSH and non-340B hospitals are shown in Table 1.

Table 1:
Summary of Findings for Minnesota

Metric	340B DSH Hospitals	Non-340B Hospitals
Dually Eligible as a Percent of Total Patients (2019)	20.1%	10%
Disability Insurance Recipients as a Percent of Total Patients (2019)	30.3%	18.3%
Black/African American as a Percent of Total Patients (2019)	3.9%	1.2%
Medicaid Revenue as a Percent of Hospital Operating Revenue (FY 2018)	10.6%	6.3%

Discussion

The results of these analyses show that in Minnesota relative to non-340B hospitals, 340B DSH hospitals serve a higher percentage of patients who are experiencing low incomes and/or are eligible for Medicare because of a disability. They also serve a higher proportion of those identifying as Black/African American than do non-340B hospitals. 340B hospitals also provide the majority of hospital care to Medicaid patients. As with national data, the data for Minnesota indicate that the 340B program is appropriately targeted and inherently recognizes the special challenges that 340B hospitals face in providing care to these populations. 340B is critical to the continued operations of many eligible entities.

National results for the L&M[10] and Dobson|DaVanzo[11] studies can be found at 340BHealth.org.

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[1] Dobson, A., Murray, K., & DaVanzo, J. (2020). *The Role of 340B hospitals in serving Medicaid and low-income Medicare patients*. Dobson DaVanzo & Associates.
https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf

[2] L&M Policy Research, LLC. (2019). *A comparison of characteristics of patients treated by 340B and non-340B providers.*
https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf

[3] Esarey, D. & Patrick, J. (2022, May 17). *Accounting for Risk Among Dual Eligible Beneficiaries*. CareJourney. Retrieved May 31, from https://carejourney.com/accounting-for-risk-among-dual-eligible-beneficiaries/

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March 22, 2024
House Commerce Finance and Policy Committee

Chair Stephenson and Committee Members,

As 340B covered entities, we are writing to express our collective support for House File 4991 (Lislegard), legislation that will prohibit drug manufacturers from denying hospitals, community health centers, and Ryan White clinics drug discounts provided by the federal 340B Drug Program.

The 340B Drug Pricing program which was enacted by Congress in 1992 provides a way for critical health care providers ("covered entities") to purchase discounted drugs from participating pharmaceutical companies. To qualify to participate in 340B, covered entities like community health centers, sexually transmitted infection clinics and hospitals must serve a disproportionate share of low-income patients or patients living in isolated rural communities. The program allows providers to offer more comprehensive services by stretching scarce resources as far as possible to give patients access to the healthcare services they need.

Currently, when drug companies deny the required discounted prices to contract or community pharmacies, they undermine the purpose of the federal 340B program, placing further significant financial strain on healthcare providers that rely on 340B savings to provide services to the low-income, underserved, and vulnerable.

There are currently over 30 drug manufacturers that are arbitrarily denying 340B pricing to safety net providers across the country. In 2021, nationwide restrictions from 21 drug manufacturers on community and specialty pharmacies accounted for the loss of **$8.4 billion in funding from drug manufacturers**. Today, the number of drug manufacturers denying 340B pricing continues to grow, diverting millions of health care dollars from crucial health care providers across the country. These dollars are vital for ensuring underserved patients continue to have access to high quality, local health care services regardless of their income or zip code.

We urge your support of HF 4991 which will safeguard the integrity of the 340B program, ensure equitable access to comprehensive health care services for all Minnesotans, particularly those in rural or low-income areas, and support the financial stability of health care providers serving these communities. This action is not just a matter of health policy but a crucial step towards health equity, ensuring that the benefits of the 340B program reach those it was intended to help.

Allina Health
Astera Health
Avera Health

CentraCare
Children's Minnesota
Essentia Health
Fairview Health Services
Health Partners
Hennepin Healthcare
Lakewood Health System
Minnesota Association of Community Health Centers
Minnesota Community Care
Minnesota Hospital Association
Minnesota Society of Health-System Pharmacists
Olmstead Medical Center
Open Door Health Center
Rainbow Health
Sanford Health
Southside Community Health Services
The Aliveness Project
Welia Health