



340B HEALTH

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.

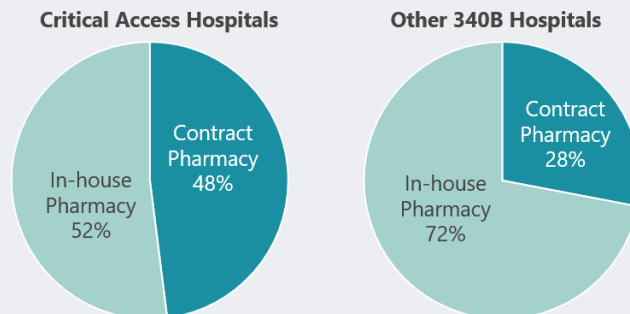
FINDINGS

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.

340B Hospitals Depend on Relationships with Community and Specialty Pharmacies

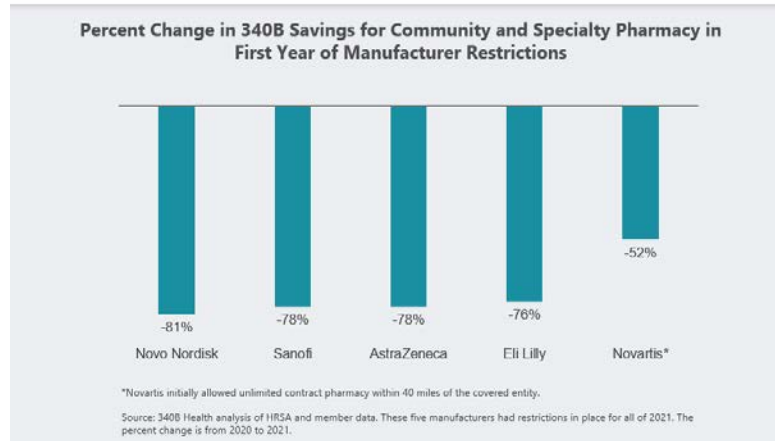
Share of 340B Savings from Community and Specialty Pharmacies, 2022



Source: 340B Health Annual Survey, Nov.-Dec. 2022.

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.

340B Savings Plummeted As Drugmakers First Imposed Restrictions—New Restrictions Are Tighter



\$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.

Contract Pharmacy Savings Associated with Restricted Drugs Has Grown to Over \$8 Billion



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.

¹102nd Congress, Second Session. (1992). H.R. No. 102-384, Part II.

² 340B Health. 2021 340B Health Annual Survey: 340B Continues to Support Essential Programs and Services in the Face of Significant Financial Stress on Hospitals. Apr 2022.

³ 340B Health analysis of 340B Health Annual Survey, Nov-Dec 2022.

⁴ 340B Health Annual Survey 2022: Vital 340B Supported Services Threatened as Manufacturer Restrictions Cut Into Savings. Jul 2023. https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf

⁵ 340B Health. Manufacturer Limits on Community Pharmacy Discounts Hurt Finances of 340B Hospitals, Harm Patients. Jan 2022. https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Findings_January_2022_FINAL.pdf

⁶ 340B Health. Restrictions on 340B Contract Pharmacy Increase Drug Company Profits but Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals. Mar 2023. https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf

⁷ 340B Health, Mar 2023.

⁸ 340B Health, Mar 2023.

⁹ 340B Health Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients. Mar 2022. https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf

-
- ¹⁰ 340B Health, Mar 2023.
- ¹¹ 340B Health analysis of 340B Health Annual Survey, Nov-Dec 2022.
- ¹² Dobson and DaVanzo Health Economics Consulting. 340B DSH Hospitals Serve Higher Share of Patients with Low Incomes. 26 Sep 2022 https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf
- ¹³ Dobson and DaVanzo Health Economics Consulting. 340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress. Jul 2022. https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf
- ¹⁴ 340B Health, Jul 2023.
- ¹⁵ 340B Health, Jul 2023.
- ¹⁶ Dobson and DaVanzo, Sep 2022.
- ¹⁷ 340B Health, Mar 2023.
- ¹⁸ 340B Health, Mar 2023.
- ¹⁹ 340B Health, Jul 2023.
- ²⁰ Dobson and DaVanzo, Sep 2022.
- ²¹ 340B Health, Jul 2023.
- ²² 340B Insight Podcast. Episode 74: A Deeper Dive into Claims Submission Conditions. 5 Jun 2023.
- ²³ This estimate is based on 340B Health analysis of HRSA contract and non-contract pharmacy volume and member savings data. Industry estimates of total program size provide a check on this estimate. (Drug Channels. The 340B Program Climbed to \$44 Billion in 2021—With Hospitals Grabbing Most of the Money. 15 Aug 2022. <https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html>) Survey data shows that contract pharmacy represents about a quarter of 340B savings overall.
- ²⁴ Dickson S. Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases. *JAMA Netw Open*. 2020;3(9):e2016388. <https://pubmed.ncbi.nlm.nih.gov/32915237/>
- ²⁵ IQVIA Institute. The Use of Medicines in the U.S. May 2021. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>.
- ²⁶ The Use of Medicines in the U.S. May 2022. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022>
- ²⁷ IQVIA. U.S. National Pharmacy Market Summary, 2021. <https://www.iqvia.com/-/media/iqvia/pdfs/us/publication/us-pharmacy-market-report-2021.pdf> and Drug Channels Institute. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. 2022.
- ²⁸ 340B Health analysis of 340B Health Annual Survey, Nov-Dec 2022.
- ²⁹ Drug Channels Institute, March 2022, and Drug Channels Institute. Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020? 12 Dec 2019. <https://www.drugchannels.net/2019/12/insurers-pbms-specialty-pharmacies.html>
- ³⁰ Specialty drugs are defined as any drug included on the specialty drug lists of at least one of the four largest specialty pharmacy companies. These include: [CVS Specialty](#), [Accredo](#), [Optum](#), and [Alliance Rx](#). Lists accessed January 2023.
- ³¹ Turner, Wesli H. MSc; Kay, Emma Sophia PhD; Raper, James L. PhD, CRNP, JD; Implementation of a Novel Clinic/Community Partnership Addressing Food Insecurity Among Adults With HIV in the Southern United States: A Program Brief. *Journal of the Association of Nurses in AIDS Care* ():10.1097 <https://www.medrxiv.org/content/10.1101/2022.04.29.22274433v1>
- ³² Jons EA, Linas BP, et al. Budgetary impact analysis of a primary care-based hepatitis C treatment program: Effects of 340B Drug Pricing Program. *PLoS One*. 2019 Mar 14;14(3):e0213745. <https://pubmed.ncbi.nlm.nih.gov/30870475/>
- ³³ Malouin R, Mckernan L, et al. Impact of the 340B Pharmacy Program on Services and Supports for Persons Served by Hemophilia Treatment Centers. *Matern Child Health J*. 2018;22(9). <https://pubmed.ncbi.nlm.nih.gov/29948762/>
- ³⁴ Institute for Clinical and Economic Review (ICER). Unsupported Price Increase Report. [2019](#), [2021](#), [2022](#).
- ³⁵ Rome B, Egilman AC, Kesselheim AS. Trends in Prescription Drug Launch Prices, 2008-2021. *JAMA*, 327:21, 7 Jun 2022.
- ³⁶ GoodRx.com. Accessed 21 Jun 2023. Price for Walgreens. <https://jamanetwork.com/journals/jama/article-abstract/2792986>
- ³⁷ Analysis of specialty drug lists from [CVS Specialty](#), [Accredo](#), [Optum](#), and [Alliance Rx](#), accessed January 2023. <https://www.statista.com/statistics/318206/revenue-of-humira/>
- ³⁸ Institute for Clinical and Economic Review (ICER). Unsupported Price Increase Report. [2019](#), [2021](#), [2022](#).
- ³⁹ 340B Health analysis of 340B Health 2022 Annual Survey data. Nov-Dec 2022.
- ⁴⁰ Accredo website: https://www.accredo.com/pharma/patient_care. Accessed 10 Mar 2023.
- ⁴¹ 340B Health, Mar 2022.
- ⁴² 340B Health. Letter to HRSA on J&J tightened restrictions. Mar 2023. https://www.340bhealth.org/files/340B_Health_Letter_to_HRSA_JJ_Final_March_21_2023.pdf