A Matter of Life, Death, & Healthcare Equity: The 340B program

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A Sage Analysis

Executive Summary

Sage Policy Group (Sage) reviewed and analyzed the federal government's 340B Drug Pricing Program. Congress enacted the 340B program in 1992 to assist safety-net providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Policymakers created the 340B program in part as a quid pro quo. Congress conditioned manufacturers' eligibility for Medicare Part B and Medicaid, two of the nation's largest health insurance programs, on participation in 340B.

The economic underpinnings of the 340B program are reasonably straightforward. While upfront development costs are massive, revenues inuring from successful drug introduction can be astronomical. From 2000 to 2018, 35 large pharmaceutical companies reported cumulative revenue of $11.5 trillion, gross profit of $8.6 trillion, and net income approaching $2 trillion.

Drug companies can generate these large profits because their marginal costs of production are low. As production is scaled, profit per unit produced surges. For instance, a 2018 study estimated the cost to produce a vial of analog insulin, the type used by most patients, at between $2 and $4. A report published earlier this year indicates that today one vial can cost $250. Some people require six vials per month. Given those low marginal costs, there is an opportunity to supply people from disadvantaged circumstances with useful, often lifesaving and extending therapies at meaningfully discounted prices without unduly impacting pharmaceutical industry profits.

Due in part to concerns expressed by pharmaceutical manufacturers and restrictions imposed by them unilaterally on the 340B program, there is an ongoing debate regarding potential changes to program implementation. This report estimates the likely impacts of several of those potential modifications, which are largely designed to shrink the program's reach.

ANALYZED PROPOSED CHANGES

Many proposed programmatic changes have been addressed in this report. Prospective impacts of two proposed programmatic modifications are modeled in this report. These are:

- disallowance of patients with incomes greater than 200 percent of federal poverty levels;
- that the number of contract pharmacies serving a community health center (often serving vast areas with multiple sites) be limited to those located near the covered entity.

PRINCIPAL ANALYTICAL FINDINGS

- Were an income limitation of 200 percent of the federal poverty level imposed, nearly 3.4 million patients at consolidated health centers and Ryan White programs would lose access to 340B benefits nationally;
- The estimated loss of patients by health centers, Ryan White HIV/AIDS programs, and hemophilia treatment centers would generate an estimated 2 million emergency department visits annually across the nation. At an average cost of $570 per visit, these visits would generate total cost of exceeding $1.1 billion;
- Based on 2020 data, government programs would finance 62 percent of these additional emergency department visits.

CONCLUSION

Proposed modifications to the 340B program would result in:

- Massive inconvenience to patients, especially in rural communities;
- Loss of access to life-enhancing and life-saving drugs for millions of patients;
- Expanded numbers of emergency room visits and associated taxpayer expense;
- Likely closure of many healthcare delivery sites presently maintained by community health centers, with rural areas sustaining disproportionate loss.
- Increased costs to taxpayers for emergency department visits by former 340B Program beneficiaries.

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Introduction

NATURE OF THE ENDEAVOR

Sage Policy Group (Sage) reviewed and analyzed the federal government's 340B Drug Pricing Program. The program has become a source of tension between certain pharmaceutical companies and healthcare providers who serve low-income patients and communities. Congress enacted the 340B program in 1992 to guarantee prescription drug discounts for medically vulnerable populations. The program is also intended to financially empower providers operating in underserved areas to maximize resources by purchasing drugs from participating manufacturers at discounted rates.

Policymakers created the 340B program in part as a *quid pro quo*. Congress conditioned manufacturers' eligibility for Medicare Part B and Medicaid, two of the nation's largest health insurance programs, on participation in 340B.[1] Pharmaceutical companies also benefit massively from contributions to basic research by federal laboratories, federal grants to university researchers, and FDA drug approval processes as well as patent and other judicial support.

The 340B program has been subject to numerous reviews and assessments by the federal government and other stakeholders over time. These studies have generated various recommendations regarding possible changes to the program.

The economic underpinnings of the 340B program are reasonably straightforward. Developing new drugs is an expensive process riddled with uncertainty. Approximately 12 percent of drugs entering clinical trials are ultimately approved by the FDA for market introduction. Recent studies estimate the average R&D cost per new drug at somewhat below $1 billion to more than $2 billion per drug.[2] In 2019, the pharmaceutical industry spent $83 billion on R&D. Adjusted for inflation, that amount is approximately 10 times what the industry spent per annum during the 1980s.[3]

Some estimates of drug development costs are even larger. The Tufts Center for the Study of Drug Development has conducted several studies over time. In 2003, the Center's estimate was that drug development cost $802 million (about $1 billion in $2013) for drugs first tested in human subjects for the time period 1983-1994. A subsequent analysis covered the period 1995-2007 and concluded that the cost to develop a new drug had risen to $2.6 billion.[4]

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[1] In 1992, about 29 million people enrolled in Medicaid at a cost of $120 billion. In 2018, more than 76 million people enrolled at a cost of $616 billion. Medicaid and CHIP Payment and Access Commission, MACStats: Medicaid and CHIP Data Book, at 27-28 (Dec. 2019), *available at* https://www.macpac.gov/wp-content/uploads/2020/01/MACStats-Medicaid-and-CHIP-Data-Book-December-2019.pdf (last visited Nov. 4, 2021). Cited in Sanofi-Aventis v. U.S. Department of HHS, et al,, November 5, 2021.

2 "Research and Development in the Pharmaceutical Industry", Congressional Budget Office (CBO), April 2021. https://www.cbo.gov/publication/57126

[3] Id.

[4] "Tufts CSDD: Cost to Develop New Drug is $2.6B", Applied Clinical Trials, November 18, 2024. https://www.appliedclinicaltrialsonline.com/view/tufts-csdd-cost-develop-new-drug-26b

While upfront costs are massive, revenues inuring from successful drug introduction can be astronomical. From 2000 to 2018, 35 large pharmaceutical companies reported cumulative revenue of $11.5 trillion, gross profit of $8.6 trillion, and net income approaching $2 trillion. As indicated by an article sourced from the National Library of Medicine, from 2000 to 2018, "the profitability of large pharmaceutical companies was significantly greater that other large, public companies . . ."[5]

Drug companies can generate these large profits because their marginal costs of production are low. As production is scaled, profit per unit produced surges. For instance, a 2018 study estimated the cost to produce a vial of analog insulin, the type used by most patients, at between $2 and $4.[6] A report published earlier this year indicates that today one vial can cost a consumer $250. Some people require six vials per month.[7] Given those low marginal costs, there is an opportunity to supply people from disadvantaged circumstances with useful, often life-saving and extending therapies at meaningfully discounted prices without unduly impacting pharmaceutical industry profits.

METHODOLOGY

This report is an exercise in estimated impact measurement associated with several modifications that have been proposed for the 340B program. Input data and informational sources include federal agencies like the Department of Health and Human Services, the Congressional Research Service and the Government Accountability Office as well as stakeholders such as the American Hospital Association and ASAP 340B, an organization supported by the pharmaceutical industry. Sage's policy impact analyses are largely based on data available from the Health Resources and Services Administration (HRSA), which administers the 340B program, and the National Association of Community Health Centers (NACHC), which represents a major category of covered entities.

Data from NACHC provide quantitative portraits of health center services and the communities they serve for each state and for Congressional districts. While data from NACHC and HRSA provide a basis for estimating impacts of some of the proposed modifications to the program on certain caregivers participating in the 340B program, these data do not provide a basis for estimating key potential impacts for all program participants, including disproportionate share hospitals (DSHs).

[5] Ledley, F. D., S. S. McCoy, G. Vaughan, and E. K. Cleary. "Profitability of large pharmaceutical companies compared with other large public companies [published online March 3, 2020]." JAMA. doi 10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054843/
[6] "Insulin's high cost goes beyond drugmakers to industry's price mediators", CNN.com, by Arthur Allen, Kaiser Health News. March 9, 2023. https://www.cnn.com/2023/03/09/health/insulin-cost-khn-partner/index.html
[7] "Insulin prices: How much does insulin cost?", SingleCare. https://www.singlecare.com/blog/insulin-prices/

340B Program Overview

Congress created the 340B Drug Pricing Program in 1992 as part of the Veteran's Health Care Act. Congress established the program to enable healthcare providers serving low-income and uninsured patients to purchase drugs at lower costs. The Health Resources and Services Administration (HRSA), a part of the U.S. Department of Health and Human Services (HHS), administers the program.[8]

Authorizing legislation requires drug manufacturers that participate in the Medicaid Program to offer outpatient drugs at discounted prices to "covered entities" of the program. These covered entities include federally qualified health centers (FQHCs) and other healthcare providers receiving federal grants to serve uninsured and low-income patients. These federal grantee entities include Native Hawaiian Health Centers, Tribal and Urban Indian Organizations, family planning projects, AIDS drug purchasing assistance programs, black lung clinics, and hemophilia diagnostic treatment centers. Hospitals participating in the program include critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and disproportionate share hospitals (DSHs). DSHs are defined as hospitals that serve a disproportionate share of low-income patients who qualify for Medicare and Medicaid.

Trends in drug prices since the 1980s underscore the reasoning behind the 340B program. Between 1984 and 2021, the producer price index for all commodities rose approximately 123 percent while the index for pharmaceuticals expanded more than 427 percent.

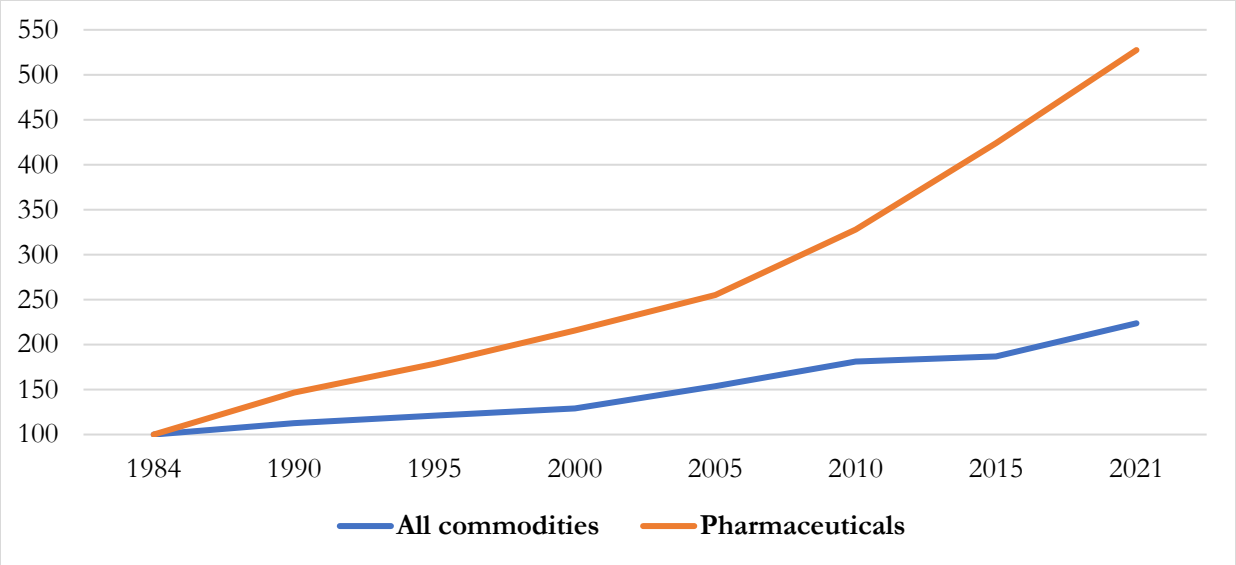
Exhibit 1 reflects the deviation in drug prices and economywide prices over time. To state it differently, between 1984 and 2021, all producer prices for all commodities increased at an average annual rate of 2.2 percent. During the same period, pharmaceutical prices increased at an average annual rate of 4.6 percent.[9] A recent assessment of prescription drug prices in America compared to 32 other countries found that U.S. prices were 256 percent of the prices in comparison countries. After adjusting for rebates and other discounts, U.S. prices were a still lofty 190 percent of those in other countries.[10]

[8] The discussion of the 340B program is based on several documents including Congressional Research Service, "Overview of the 340B Drug Discount Program," October 14, 2022 https://crsreports.congress.gov/product/pdf/IF/IF12232; "Sec. 340B Public Health Service Act" www.hrsa.gov>phs-act-section-340b; American Hospital Association, "Fact Sheet: The 340B Drug Pricing Program," March 2023 https://www.aha.org/fact-sheets/fact-sheet-340b-drug-pricing-program; National Association of Community Health Centers, "340B: A Critical Program for Health Centers," June 13, 2002 https://www.nachc.org/report-340b-a-critical-program-for-health-centers/

[9] "Drug prices outpaced inflation since the 1990s" https://usafacts.org/articles/drug-prices-outpaced-inflation-since-the-1990s/

[10] Mulcahy, Andrew W. et al, "International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies," Office of the Assistant Secretary for Planning and Evaluation, Jul 1, 2022 https://aspe.hhs.gov/reports/international-prescription-drug-price-comparisons

Exhibit 1: Trends in Producer Price Indexes for Pharmaceuticals and All Commodities, 1984 - 2021



Source: U.S. Bureau of Labor Statistics

Benefits of discounted medication prices for patients can be dramatic. As a straightforward example, a patient at a health center in Columbus, Ohio relies on the 340B program to render daily doses of insulin required to treat her diabetes affordable. With assistance from the health center where she receives care, a 90-day supply of insulin is available for less than $15. Without this support, that supply of insulin would cost more than $1,000, more than that patient or many others could afford. Without daily doses of insulin, the patient indicates that her kidneys would stop functioning and she would die.[11] This is the type of circumstance that explains the creation of and ongoing support for the 340B program.

Beneficial impacts span well beyond drug savings among patients in need. Savings that covered entities realize from reduced costs of pharmaceutical products support and extend the services they provide to vulnerable communities. In particular, savings on life-saving and life-enhancing drugs stretch limited federal resources available to support poorer communities so that more individuals can be served and more comprehensive services provided. Additional support may include free care for uninsured patients, free vaccines, expanded care for dental, behavioral health, and specialty needs.

Since its creation in 1992, Congress has contemporized the 340B program with subsequent legislation. The Patient Protection and Affordable Care Act (ACA) of 2010 expanded the list of covered entities by adding children's hospitals, cancer treatment facilities, critical access hospitals, rural referral centers, and sole community hospitals that disproportionately serve those with low incomes.[12] After the

[11] Farber, Any Simmons, "Community Health Center Leaders Defend the 340b Drug Discount Program Against Rx Manufacturer Attacks," September 16, 2020. https://www.nachc.org/community-health-center-leaders-defend-the-340b-drug-discount-program-against-rx-manufacturer-attacks/

[12] H.R.3590 - Patient Protection and Affordable Care Act, Congress.gov. https://www.congress.gov/bill/111th-congress/house-bill/3590

passage of the ACA, the number of hospitals participating in the 340B program tripled. By October 2022, there were more than 53,000 covered entities. In 2022, the Consolidated Appropriations Act allowed certain covered entities disqualified from the 340B program during the pandemic because of reduced services delivered to vulnerable patients to be reinstated.[13]

To support policymaking and programmatic refinements, the Government Accountability Office (GAO) has conducted 340B program studies and audits. A December 2019 GAO report found that more than two-thirds of covered entities were nongovernmental hospitals with state and local government contracts to provide care to low-income patients ineligible for Medicare and Medicaid. GAO recommended that HRSA increase its oversight of these entities to ensure that they meet program eligibility requirements.

Another GAO recommendation called for HRSA and the Centers for Medicare & Medicaid (CMS) to improve oversight of the 340B program and the Medicaid Drug Rebate program to ensure that covered entities are not receiving duplicate discounts for 340B program drugs. State Medicaid programs may request manufacturer rebates on certain drugs prescribed to Medicaid patients. Drugs purchased through the 340B program are not eligible for these Medicaid rebates. GAO found that CMS had not always tracked state policies and procedures to prevent duplicate discounts.[14]

In recent years, drug manufacturers have challenged the use of contract pharmacies by covered entities. Because many covered entities do not have in-house pharmacies, they rely on contracts with outside retail pharmacies to dispense drugs to their patients. Manufacturers have argued that the increase in the number of contract pharmacies has generated growing fraud and abuse in the 340B program.

In response, some manufacturers-imposed restrictions on covered entities that use contract pharmacies to purchase 340B medications. For example, in 2020, Sanofi, Eli Lilly, and AstraZeneca issued policies such as stopping the distribution of drugs through contract pharmacies, requiring covered entities to submit claims-level data for drugs dispensed through contract pharmacies, or restricting the number of contract pharmacies to one per covered entity if the covered entity did not have an in-house pharmacy and did not provide claims-level data.[15] HRSA issued violation letters to manufacturers indicating that their restrictions on covered entities using contract pharmacies were in violation of the 340B program.

[13] H.R.2471 - Consolidated Appropriations Act, 2022, Congress.gov. https://www.congress.gov/bill/117th-congress/house-bill/2471
[14] Congressional Research Service, "Overview of the 340B Drug Discount Program," October 14, 2022 https://crsreports.congress.gov/product/pdf/IF/IF12232
[15] Sanofi-Aventis US, LLC v. US Department of Health and Human Services, Dist. Court, D. New Jersey 2021 https://scholar.google.com/scholar_case?case=15280375503961196171&hl=en&as_sdt=5,33&sciodt=3,33

Manufacturers brought suits in four federal district courts across the country arguing that their restrictions were valid. The courts reached different conclusions regarding the validity of manufacturer-imposed restrictions. Three of the cases were appealed to federal Courts of Appeals. The different outcomes in these cases could create more uncertainty with respect to the use of contract pharmacies. Lingering uncertainty could also result in the imposition of additional restrictions on covered entities seeking to access 340B drug pricing benefits on behalf of their constituents.

SIGNIFICANT GROWTH IN 340B PROGRAM PURCHASES AS NEED EXPANDS

PROVIDER PERSPECTIVE

The 340B program has expanded dramatically in recent years. Between 2015 and 2021, the total value of discounted purchases made under the 340B program grew 260 percent at an average annual growth rate of 23.8 percent. As reflected in Exhibit 2, covered entities purchased $43.9 billion of discounted pharmaceutical products in 2021, a nearly four-fold increase from the $12.2 billion of purchases in 2015. The value of 2021 purchases at list prices was $93.6 billion, almost triple the value at list prices of products purchased in 2015.

Over time, the rate of discount has consistently declined. In 2021, the value of discounts on 340B program purchases was 53 percent of the list prices of those purchases. In 2015, the value of discounts was 63 percent of list prices. While the rate of discount has declined since 2015, the absolute value of discounts has grown substantially, from $20.4 billion to $49.7 billion.[16] Not only do those discounts translate into savings and access for patients in financial and medical need, they also represent significant support to those that help form the nation's healthcare safety net.

Exhibit 2: 340B Program Discounted Purchases by Covered Entities, 2015-2021 ($ Billions)

	Value of discounted purchases	Value at list prices	Value of discounts	Discounts as share of list prices
2015	$12.2	$32.6	$20.4	63%
2016	$16.2	$40.5	$24.3	60%
2017	$19.3	$45.5	$26.2	58%
2018	$24.3	$57.6	$33.3	58%
2019	$29.9	$67.8	$37.9	56%
2020	$38.0	$80.7	$42.7	53%
2021	$43.9	$93.6	$49.7	53%

Source: Drug Channels

Hospitals, especially disproportionate share hospitals, dominate the share of purchases made via the 340B program. As indicated in Exhibit 3, in 2021, hospitals purchased more than $38 billion of

[16] Fein, Adam J., "The 340B program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money," Drug Channels, December 16, 2022 https://www.drugchannels.net/2022/12/the-340b-program-climbed-to-44-billion.html

discounted pharmaceutical products, representing almost 87 percent of total purchases. Disproportionate share hospitals accounted for nearly 90 percent of hospital purchases through the 340B program and 78 percent of all 340B program purchases.

Healthcare providers that are federal grantees accounted for slightly more than 13 percent of total 340B program purchases in 2021. Consolidated health center programs and Ryan White HIV/AID programs accounted for about three-quarters of the purchases made by federal grantees.[17]

Exhibit 3: 340B Program Discounted Purchases by Type of Covered Entities, 2021 ($ Millions)

	Value of discounted purchases in 2021	Share of total
Hospitals		
Disproportionate Share Hospitals	$34,288.5	78.1%
Children's Hospitals	$1,330.2	3.0%
Rural Referral Centers	$1,174.2	2.7%
Critical Access Hospitals	$620.9	1.4%
Sole Community Hospitals	$451.6	1.0%
Free-standing Cancer Centers	$304.1	0.7%
Subtotal	$38,169.5	86.9%
Federal Grantees		
Consolidated Health Center Programs	$2,215.2	5.0%
Ryan White HIV/AIDS Programs	$2,180.0	5.0%
Sexually Transmitted Disease Clinics	$871.0	2.0%
Comprehensive Hemophilia Treatment Centers	$192.1	0.4%
All other	$284.6	0.6%
Subtotal	$5,742.9	13.1%
Total	$43,912.4	100.0%

Source: Drug Channels

In 2021, there were more than 55,000 covered entities in the 340B program. Exhibit 4 supplies pertinent summary detail. Like 340B program purchases, disproportionate share hospitals are the most common form of covered entity, representing almost 45 percent of all total entities. Collectively, hospitals account for more than 60 percent of all covered entities. The second most common type of covered entity is consolidated health center programs, which accounted for nearly 22 percent of all covered entities. Federal grantees accounted for more than 39 percent of covered entities.[18]

Based on the value of purchases made by types of covered entities indicated in Exhibit 3, the average value of 340B program purchases per covered entity can be computed. As reflected in Exhibit 4, these average annual values vary considerably. The largest average purchases per covered entity were made by Ryan White HIV/AIDS program grantees and free-standing cancer centers, both of which

[17] Ibid.
[18] HRSA Office of Pharmacy Affairs 340B OPAIS https://340bopais.hrsa.gov/CoveredEntitySearch

had average purchases of roughly $2 million per entity in 2021. The next largest average purchases were made by disproportionate share hospitals and comprehensive hemophilia treatment centers, which generated average purchases of roughly $1.3 million. Alternatively, consolidated health centers and critical access hospitals had average purchases of less than $200,000. The smallest average purchases — less than $65,000 — were made by all other federal grantees, a group that includes family planning centers, tuberculosis clinics, Native American and Native Hawaiian program grantees, and black lung clinics.

Given the estimated average value of the 340B program discounts in 2021, which are depicted in Exhibit 2, it is also possible to calculate the average value of these discounts for each type of covered entity. The value of these discounts is slightly greater than the discounted purchase prices and reflects the wide variation in the average value of discounted purchases.

Exhibit 4: Number of 340B Program Covered Entities and Average 340B Purchases, 2021

	No. of covered entities	Share of total	Value of discounted purchases per entity	Value of discounts per entity
Hospitals				
Disproportionate Share Hospitals	24,912	44.6%	$1,376,385	$1,558,231
Children's Hospitals	1,736	3.1%	$766,244	$867,479
Rural Referral Centers	2,058	3.7%	$570,554	$645,935
Critical Access Hospitals	3,998	7.2%	$155,303	$175,821
Sole Community Hospitals	1,072	1.9%	$421,269	$476,926
Free-standing Cancer Centers	160	0.3%	$1,900,625	$2,151,733
Subtotal	33,936	60.7%	$1,124,750	$1,273,350
Federal Grantees				
Consolidated Health Center Programs	12,145	21.7%	$182,396	$206,494
Ryan White HIV/AIDS Programs	1,082	1.9%	$2,014,787	$2,280,978
Sexually Transmitted Disease Clinics	4,170	7.5%	$208,873	$236,469
Comprehensive Hemophilia Treatment Centers	147	0.3%	$1,306,803	$1,479,455
All other	4,395	7.9%	$64,755	$73,311
Subtotal	21,939	39.3%	$261,767	$296,351
Total	**55,875**	**100.0%**	**$785,904**	**$889,737**

Sources: Drug Channels, HRSA Office of Pharmacy Affairs

PATIENT PERSPECTIVE

Another perspective on average 340B purchases is the average value of these purchases for patients served by covered entities. Data regarding the specific number of patients served, however, are limited to health centers and Ryan White HIV/AIDS programs. Health Center Program awardees and look-alikes served more than 31 million patients in 2021.[19] Ryan White HIV/AIDS program grantees served nearly 600,000 patients in 2021.[20] A rough estimate of the number of patients at hemophilia treatment centers is based on the total number of affected individuals in the United States. According to HRSA, there are 40,000 people affected by hemophilia.[21]

Given these program-specific patient estimates, the value of 340B program purchases per patient can be estimated as summarized in Exhibit 5. These calculations reflect a wide range of average values for purchases, with health centers making average purchases of $71 per patient and Ryan White HIV/AIDS programs and Hemophilia Treatment centers making purchases of $3,784 and $4,803, respectively. This calculation of the average purchases per hemophilia patient is likely to underestimate the actual value because it assumes all those affected by hemophilia are patients at HRSA-funded treatment centers.

Exhibit 5: Number of Patients at Selected 340B Program Covered Entities and Average 340B Purchases Per Patient, 2021

Federal grantees	Number of patients	Value of discounted purchases per patient
Consolidated Health Center Programs	31,148,343	$71
Ryan White HIV/AIDS Programs	576,076	$3,784
Comprehensive Hemophilia Treatment Centers	40,000	$4,803

Sources: Drug Channels, HRSA, NACHC

These calculations demonstrate how critical 340B program benefits are at the microeconomic or patient level. For covered entities, average purchase values represent a significant operational expenditure. Accordingly, the value of discounts constitutes a significant opportunity to fund operations and more broadly support healthcare safety nets. For patients of Ryan White HIV/AIDS programs and hemophilia treatment centers, average purchase values demonstrate how expensive medications can be for patients. Because these entities are intended to focus on low income patients, the cost of these medications is almost certainly unaffordable for their patients. Yet the cost of these discounted prescriptions would also be challenging for middle income and possibly even more affluent patients to afford. Without these medications, the ability to provide effective and comprehensive healthcare is almost certainly impossible in many instances.

[19] "2021 Patient Characteristics Snapshot" data.HRSA.gov https://data.hrsa.gov/tools/data-reporting/data-snapshot
[20] "Ryan White HIV/AIDS Program (RWHAP) Compass Dashboard" data.HRSA.gov https://data.hrsa.gov/topics/hiv-aids/compass-dashboard
[21] "National Hemophilia Program" https://mchb.hrsa.gov/programs-impact/programs/national-hemophilia-program

MEDICAID DRUG REBATE PROGRAM

The Medicaid Drug Rebate Program (MDRP) is another federal program that reduces the cost of outpatient prescription drugs dispensed to Medicaid patients. The MDRP involves the Centers for Medicare and Medicaid Services, state Medicaid agencies, and approximately 780 drug manufacturers. The program encompasses all 50 states and the District of Columbia.

Under the program, drug manufacturers enter a National Drug Rebate Agreement with the U.S. Department of Health and Human Services that enables state Medicaid coverage for most manufacturers' drugs. Covered outpatient drugs under the program are subject to rebates from manufacturers. These rebates are paid on a quarterly basis to states and are shared between states and the federal government to offset the costs of prescription drugs administered by the Medicaid program. A requirement for drug manufacturers to participate in the MDRP is that they also have a pricing agreement for the 340B program.[22]

Exhibit 6 summarizes MDRP spending since 2018. Over that period, gross spending expanded more than 29 percent to in excess of $80 billion. Net spending increased even faster, 46 percent, to over $38 billion. While the total value of rebates grew more than 17 percent to over $42 billion, the value of rebates as a share of gross spending fell from 58 percent in 2018 to 53 percent in 2021.

Exhibit 6: MDRP Purchases and Rebates by Covered Entities, 2015-2021 ($ Billions)

	Gross spending	Net spending	Value of rebates	Rebates as share of gross spending
2018	$62.3	$26.1	$36.2	58%
2019	$68.2	$31.1	$37.1	54%
2020	$71.8	$32.6	$39.2	55%
2021	$80.6	$38.1	$42.5	53%

Source: Medicaid and CHIP Payment and Access Commission

In 2021, the Medicaid rebate as a percentage of list price available to states and the federal government was equivalent to the 340B discount. Both are defined as a percentage of average manufacturer price.[23] Unlike the MDRP rebates paid to states, 340B discounts are benefits to covered entities that participate in the 340B program. The 340B benefits are derived from the difference between the discounted price and the reimbursement that third parties pay covered entities for medications. Because MDRP rebates and 340B program discounts can apply to the same products, avoiding duplicate discounts for pharmaceutical products is an ongoing concern among manufacturers.

[22] "Medicaid Drug Rebate Program (MDRP)" https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html
[23] Fein, Adam J., "New HRSA Data: 340B program Reached $29.9 Billion In 2019; Now Over 8% Of Drug Sales," Drug Channels, June 9, 2020 https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html

Proposed Changes to the 340B Program

Because of the possibility of duplicate discounts, outright fraud, and a desire to measure programmatic impact on health outcomes, the 340B program has been the subject of scrutiny by various governmental and nongovernmental agencies. The Government Accountability Office (GAO), the National Association of Community Health Centers (NACHC), and ASAP 340B are among the entities that have assessed the program.

Indeed, the GAO has conducted several studies of the 340B program in support of congressional decision-makers. The two main recommendations the GAO has made are: 1) that HRSA increase oversight of covered entities to ensure that they meet program requirements. This recommendation particularly emphasized oversight of disproportionate share hospitals; and 2) that HRSA and CMS increase their oversight of the 340B and Medicaid rebate programs to ensure that covered entities are not receiving duplicate rebates or discounts on drugs covered by 340B.[24]

A recent assessment by the NACHC found the 340B program critically important to the ability of Community Health Centers to supply affordable or free outpatient medications and to invest in services meeting the unique needs of their communities.[25] The assessment determined that health centers are caught between pharmaceutical manufacturers, pharmacy benefit managers (PBMs) and health insurers, all of which want to secure a larger share of the 340B savings that health centers obtain through the program.

Several legislative fixes are identified in the NACHC assessment that would protect health centers from practices that diminish benefits derived from the 340B program. Proposed federal legislation would protect health centers from having their 340B savings redirected to PBMs or insurers. Other potential federal legislation would ensure that manufacturers ship products to contract pharmacies unconditionally. This would protect the role of contract pharmacies in the delivery of medications to health centers.

The NACHC assessment also identified nearly two dozen states that have passed legislation prohibiting PBMs from discriminating against contract pharmacies and argued for other states to enact similar legislation. These legislative efforts and administrative actions supported by NACHC would protect the 340B program from efforts to diminish the delivery of medications to health centers and their patients. It would also frustrate efforts to deflect resources away from health centers, thereby limiting their capacity to serve their segment of the healthcare safety net.

[24] Rogers, Hannah-Alise, "Overview of the 340B Drug Discount Program," Congressional Research Service, October 14, 2022
[25] National Association of Community Health Centers, "340B: A Critical Program for Health Centers," June 13, 2022 https://www.nachc.org/report-340b-a-critical-program-for-health-centers/

ASAP 340B advocates for a range of federal legislative revisions to the 340B program, proposing a much narrower definition of eligible patients to reduce the scope of qualifying prescriptions. These changes include redefining what ASAP 340B asserts is an overly broad definition of patients, which would place burdensome restrictions on what prescriptions qualify for the program, with prescriptions mandated to be issued only by directly affiliated providers.

These modifications will restrict covered entities' capacity to deliver ongoing care for chronic conditions, limiting access to essential medications for lower-income individuals by setting an income cap at 200 percent above the federal poverty level. Historically, Federal Qualified Health Centers (FQHCs) have adhered to a consistent patient definition established by HRSA's Bureau of Primary Health Care, that is utilized by GAO and aligns with the AMA's definition. Moreover, a federal court has disallowed the Office of Pharmacy Affairs (OPA) from altering this patient definition, thereby maintaining a stable federal guideline for FQHC operations.

It is also proposed that a range of restrictions be placed on contract pharmacies. Contract pharmacies would be limited, for instance, to covered entities in medically underserved areas or to prescriptions for specific populations such as those with HIV or chronic illness. It has also been proposed that the number of contract pharmacies serving a community health center (often serving vast areas with multiple sites) be limited to five.

ASAP 340B would result in severe limits on the number of contract pharmacies insisting they be near facilities. As noted above, one of the lawsuits brought by pharmaceutical manufacturers would limit contract pharmacies to one per covered entity under certain circumstances. ASAP 340 advocates for contract pharmacies to be located near where covered entities provide services, whereas 44 percent of community health centers have contract pharmacies that serve 20 or more ZIP codes.[26]

Another set of concerns focuses on so-called "child sites", which are outpatient facilities operated by disproportionate share hospitals at locations other than the hospital itself. The concern is rooted in the notion that many child sites are in areas associated with higher incomes and lower minority population shares than the actual location of affiliated hospitals. Ultimately, each of these proposals is intended to place additional limits on the 340B program's reach. Restrictions on contract pharmacies would also restrict the ability of all patients, and especially rural patients, to access the medications they need to receive the comprehensive services required for their medical conditions.

[26] Ibid.

Impact of Proposed Program Alterations

Unlike recommendations of the GAO, ASAP 340B proposals would diminish the number of patients served by covered entities. Proposed restrictions on eligible patients would reduce the number of patients served, though it is difficult to estimate the extent of that truncation. Excluding patients whose income exceeds 200 percent of federal poverty levels would also reduce the number of patients served.

Another proposed change would restrict the number of contract pharmacies for any covered entity. A similar proposed change could reduce the number of child sites for disproportionate share hospitals where services are delivered. Each of these restrictions could significantly reduce access to care for potential patients and effectively reduce the number of patients served by covered entities.

Pivotal to this analysis is the fact that specific data are only available on the number of patients served by health centers and Ryan White HIV/AIDS programs. These data provide a basis for estimating some of the principal impacts of proposed changes to the 340B program. A rough estimate of patients served by hemophiliac centers is also available. The number of patients served by other covered entities is unknown. Consequently, the ability to estimate the total impacts of proposed changes to the entire 340B program is constrained. Nonetheless, the Sage study team has been able to generate some key estimates of potential impact. These are detailed below.

ESTIMATED IMPACTS ON PATIENTS

There exists sufficient data to estimate the impact on program accessibility in the event of income restrictions in the context of consolidated health center programs and Ryan White HIV/AIDS program grantees. HRSA data regarding health center grantees and look-alikes indicate that 10.4 percent of patients served by these entities have incomes above 200 percent of federal poverty levels.[27] HRSA data regarding patients of Ryan White HIV/AIDS program grantees indicate that an estimated 20.4 percent of these patients have incomes above 200 percent of federal poverty levels.[28] Data characterizing income levels of patients of Comprehensive Hemophilia Treatment Centers are not available. To estimate this share of hemophilia patients, an average of the share of health center and Ryan White HIV/AIDS program patients is used for illustrative purposes, which translates into 15.4 percent of these patients.

[27] HRSA, "2021 Patient Characteristics Snapshot" https://data.hrsa.gov/tools/data-reporting/data-snapshot

[28] HRSA, "Ryan White HIV/AIDS Program (RWHAP) Compass Dashboard" https://data.hrsa.gov/topics/hiv-aids/compass-dashboard

Exhibit 7 summarizes the number of patients for these three forms of covered entities that would be considered ineligible for 340B program benefits if an income limitation of 200 percent of federal poverty levels was imposed. As indicated, nearly 3.4 million patients would lose access to 340B benefits. The overwhelming majority of these patients, many of whom are uninsured, would be patients of consolidated health centers.

Exhibit 7: Patients Affected by 200% Poverty Level Limit Income Restriction

	Total patients	Share with income over 200% of poverty level	Patients with income over 200% of poverty level
Consolidated health center programs	31,148,343	10.4%	3,250,309
Ryan White HIV/AIDS program grantees	576,076	20.4%	117,769
Comprehensive hemophilia treatment centers	40,000	15.4%	6,160
Total	31,764,419	10.6%	3,374,238

Source: NACHC, HRSA

While there are no readily available data regarding the number of patients served by other covered entities or the income characteristics of those patients, it is more than reasonable to assume that the more than 3.3 million patients listed in Exhibit 7 represent a small fraction of the total number of 340B program patients who would be affected by placing an income limit of 200 percent of federal poverty levels on patient eligibility.

The three types of entities listed above accounted for 10.4 percent of 340B program discounted purchases in 2021. While disproportionate share hospitals focus some of their services on low-income populations, other covered entities presumably serve a broader range of the population.

In 2021, 27.6 percent of the U.S. population was associated with incomes less than 200 percent of federal poverty levels. Accordingly, more than 72 percent of the U.S. population had incomes above that 200 percent limit, almost seven times higher than the estimated share of patients at health centers, Ryan White HIV/AIDS programs, and hemophilia treatment centers. Consequently, placing a limit of 200 percent of the poverty level on program eligibility would exclude tens of millions of other patients treated in other settings, whether at disproportionate share hospitals or at hospitals that are not disproportionate share, but still collectively serve millions of low-income patients.

IMPACTS ON RURAL COMMUNITIES

Many covered entities serve rural communities. Data characterizing community health centers indicate that 40.9 percent of these centers' delivery sites are in rural areas.[29] This reflects the fact that

[29] National Association of Community Health Centers, "State Level Health Center Data & Maps" https://www.nachc.org/state-level-data-maps/

about one in five Americans lives in a rural area and that massive distances between communities require more locations per capita. As defined by the U.S. Census Bureau, rural areas are generally sparsely populated, have low housing density, and are far from urban areas. These areas account for 97 percent of U.S. land mass.[30]

Given vast distances, providing healthcare services to scattered rural populations is already challenging. Proposals restricting the ability of covered entities to maintain contracts with pharmacies so that their patients would have greater access to prescription medications would almost certainly exert greater impact on rural communities. A primary reason for the larger impacts in rural areas is the increased likelihood that rural patients suffer greater barriers to accessing their prescriptions at contract pharmacies. An extreme example is a covered entity in Arizona that has patients who would have to travel up to 180 miles each way to fill prescriptions if they had no contract pharmacies. A covered entity in Michigan serves a 10,000-mile area and could not meet its patients' prescription needs if it was restricted to one contract pharmacy.[31] The fact that 44 percent of community health centers have contract pharmacies that serve more than 20 ZIP codes is likely another indication of the issues facing covered entities serving rural populations.

The potential impact of restricting contract pharmacies on rural communities is most clearly observable in the context of community health centers. Of the total of approximately 14,000 delivery sites, more than 5,700 are in rural areas. Assuming that patients can be prorated by the number of delivery sites, these rural delivery sites serve almost 13 million patients as indicated in Exhibit 8.

Exhibit 8: Potential Impact of Restricting Contract Pharmacies on Community Health Centers

Nature of delivery sites	Number	Patients	Share of total
Total delivery sites	14,099	31,148,343	100%
Rural delivery sites	5,762	12,729,751	40.9%

Source: National Association of Community Health Centers

The potential impact of restricting contract pharmacies on all covered entities is summarized in Exhibit 9. This assessment assumes that all rural referral centers are in fact in rural areas[32] and that for all remaining covered entities the share of rural delivery sites is the same as the share for community health centers. Based on this presumption, one in three covered entity delivery sites is likely to be in a rural area. If restrictions on contract pharmacies are enacted, these rural delivery sites are likely to be most at risk of having patients lose access to outpatient medications. While some rural patients may have access to tele-health, which is available at all community health centers in 45 states and at

[30] Census.gov, "One in Five Americans Live in Rural Areas," August 9, 2017 https://www.census.gov/library/stories/2017/08/rural-america.html
[31] Op. cit., Sanofi-Aventis US, LLC v. US Department of Health and Human Services
32 HRSA, "Rural Referral Centers" https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/rural-referral-centers

92 to 97 percent of health centers in the five remaining states, access to tele-health does not equate to ready access to prescription medicines.[33]

Exhibit 9: Potential Impact of Restricting Contract Pharmacies on All Covered Entities

Nature of delivery sites	Number	Share that are rural	Number of rural sites
Community Health Centers	14,099	40.9%	5,762
Rural Referral Centers	2,058	100.0%	2,058
All other covered entities	41,672	40.9%	17,031
Total	57,829	33.0%	19,089

Source: National Association of Community Health Centers, HRSA Office of Pharmacy Affairs

LOSING ACCESS TO THE 340B PROGRAM COULD MEAN LOSING ACCESS TO MEDICATIONS

There is a basic problem with medication prescriptions. Many prescriptions—20 to 30 percent—are never filled. For those that are filled, roughly half are not taken as prescribed, and patients typically take only about half of the doses that are prescribed. As a consequence, those who do not take their medications as prescribed increase emergency department visits and hospitalizations. Cost is an important factor in these problems. When co-pays reach $50, adherence to prescriptions decreases.[34]

Prescriptions are a common need in adults. In 2021, approximately 60 percent of those 18 and older took at least one prescription medication and 36 percent took three or more prescriptions. Many of these adults, however, reported not taking medications as prescribed. Those with disabilities or in fair to poor health were three times more likely to not take medications as prescribed as those without disabilities or those in excellent, very good, or good health. The stated reasons for not taking medications were to reduce the costs of healthcare; the percentage of patients that fail to take their prescribed medications increases as income decreases. Uninsured adults were also less likely to take medications as prescribed compared to those with some kind of health coverage, and the highest percentage of adults who did not take medications as prescribed were those who did not have prescription drug coverage.[35]

Cost is a critical factor in these decisions. One analysis found that 28 percent of adults not yet old enough to qualify for Medicare did not adhere to their prescriptions because of the high costs of these medications, and these costs have increased sharply in recent years. For instance, nearly 11 percent

[33] Op. cit., National Association of Community Health Centers
34 Brody, Jane E., "The Cost of Not Taking Your Medicine," New York Times, April 17, 2017 https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html
35 Mykyta, Laryssa and Robin A. Cohen, "Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021," NCHS Data Brief No. 470, June 2023 https://www.cdc.gov/nchs/products/databriefs/db470.htm#ref2

of American adults were diagnosed with diabetes or prediabetes as of 2017, and the annual cost of the Lantus SoloStar insulin pen used to treat these conditions had increased from $2,907 in 2012 to $4,703 in 2017. Similarly, for the roughly 83 million American adults diagnosed with high blood pressure, the annual cost of Benicar, a commonly prescribed medication, increased from $1,643 in 2012 to $3,509 in 2017.[36]

These costs not only affect the willingness of patients to adhere to prescriptions but can also become a barrier to access to healthcare itself. A 2021 report found that one in 11 adults indicated that they had delayed or did not get medical treatment because of costs, and a March 2022 poll found that 43 percent of adults reported one member of their family put off or postponed healthcare due to its cost. Those with incomes below 200 percent of the federal poverty level were far more likely to delay or go without care because of its costs. Others who were more likely to delay or go without care included those in worse health, those who are uninsured, and those who do not have usual sources of care. [37]

Losing access to 340B Program discounts on prescription medications would clearly position former patients to suffer these kinds of consequences. Under the best of circumstances, these patients may not have adhered to the requirements of their prescriptions. The absence of 340B Program discounts and the resulting higher costs would make filling prescriptions more difficult, if not impossible, likely reducing overall access to care. The most vulnerable groups in these analyses and reports—low-income households and the uninsured—are the target populations for many of the covered entities that participate in the 340B Program such as community health centers.

EFFECTS ON COMMUNITY HEALTH CENTERS AND OTHER COVERED ENTITIES

The effects of restricting 340B program eligibility to patients with incomes at or below 200 percent of the federal poverty level and potentially having patients of rural delivery sites lose access to contract pharmacies are significant. Potential impacts of these program modifications for health centers are summarized in Exhibit 10. To illustrate the effects of proposed changes, this assessment assumes that 44 percent of all rural delivery sites and patients could lose access to 340B program medications either due to income limits or restrictions on contract pharmacies that are more distant from the health center where services are delivered. This loss of medications essentially eliminates healthcare for those patients. If the remaining urban sites lost the estimated 10.4 percent of patients with incomes above

36 Bunis, Dena, "High Prescription Drug Prices Lead Many Consumers to Ignore Doctors' Orders." August 21, 2019 https://www.aarp.org/politics-society/advocacy/info-2019/drug-prices-consumer-impact.html

37 Rakshit, Shameek, et al, "How does cost affect access to healthcare?" Kaiser Family Foundation, January 30, 2022 https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care

the 200 percent poverty limit, more than 7.5 million patients would no longer benefit from the 340B program. This amounts to 24.2 percent of all current patients of health centers.

Exhibit 10: Potential Impact of 200% Income Limit and Restricting Contract Pharmacies on Community Health Centers

Nature of Delivery Sites	Number of sites	Current Patients	Share Potentially Losing Benefits	Patients Potentially Losing Benefits
Rural delivery sites	5,762	12,729,751	44.0%	5,601,090
Urban delivery sites	8,337	18,418,592	10.4%	1,921,968
Total	14,099	31,148,343	24.2%	7,523,058

Source: National Association of Community Health Centers

Among other considerations, the loss of patients would have an impact on the operating revenues of health centers. Major sources of revenue for community health centers in 2021 are supplied in Exhibit 11. The total value of health center services is based on economic impact assessments of health centers that determined that the direct output of these centers was almost $34 billion that year. Federal funds to support health centers were almost $5.5 billion.[38] The value of discounts on 340B program purchases was $2.5 billion. The remaining $26 billion in revenue emerges from insurance claims and other sources.

Exhibit 11: Revenue Sources for Community Health Centers, 2021 ($ Millions)

Revenue sources 2021	Value	Share of total
Value of drug discounts	$2,507.9	7.4%
Federal funds for health centers	$5,473.2	16.1%
Insurance, other revenue	$26,013.3	76.5%
Total value of health center services	$33,994.4	100.0%

Source: National Association of Community Health Centers

The potential loss of patients would also have a substantial impact on the revenue available to health centers as shown in Exhibit 12. A 24.2 percent reduction in 340B purchases would also generate a loss of the discounts associated with those purchases. Based on 2021 purchases, this loss of medicine/drug discounts would total over $605 million. A 24.2 percent loss of patients would presumably also reduce insurance and other patient-generated revenue by a similar percentage, estimated at more than $6.2 billion. Assuming the loss of patients did not affect federal funding of health centers, the total revenue loss resulting from proposed program restrictions is an estimated $6.9 billion, amounting to over 20 percent of total revenue for 2021.

[38] Op. cit., National Association of Community Health Centers

Exhibit 12: Potential Loss of Revenue Sources for Community Health Centers ($ Millions)

Revenue sources 2021	2021 Value	Potential Loss	Net revenue	Net revenue as share of 2021
Value of medicine discounts	$2,507.9	$605.7	$1,902.2	75.8%
Federal funds for health centers	$5,473.2	$0.0	$5,473.2	100.0%
Insurance, other revenue	$26,013.3	$6,282.8	$19,730.5	75.8%
Total value of health center services	$33,994.4	$6.888.5	$27,105.9	79.7%

Source. National Association of Community Health Centers

Assuming the potential loss of 10.4 percent of patients estimated for health centers, based on patient incomes, applied to all covered entities other than Ryan White HIV/AIDS programs and hemophilia centers, which would register a greater proportionate loss of patients, the reduction in 340B program purchases and the value of discounts linked to those purchases can be estimated. Based on 2021 activity, values of reduced purchases and the value of discounts are indicated in Exhibit 13. Reductions in 340B program purchases by all covered entities are estimated to be almost $4.6 billion or 10.4 percent of the value of all 340B program purchases in 2021.

Exhibit 13: Potential Impacts on 2021 Revenue Sources for All 340B Programs Covered Entities ($ Millions)

	Value of discounted purchases	Reduced discounted purchases	Reduced value of discounts
Hospitals			
Disproportionate Share Hospitals	$34,288.5	$3,578.0	$4,050.7
Children's Hospitals	$1,330.2	$138.8	$157.1
Rural Referral Centers	$1,174.2	$122.5	$138.7
Critical Access Hospitals	$620.9	$64.8	$73.4
Sole Community Hospitals	$451.6	$47.1	$53.4
Free-standing Cancer Centers	$304.1	$31.7	$35.9
Subtotal	$38,169.5	$3,983.0	$4,509.2
Federal Grantees			
Consolidated Health Center Programs	$2,215.2	$231.2	$261.7
Ryan White HIV/AIDS Programs	$2,180.0	$444.7	$503.5
Sexually Transmitted Disease Clinics	$871.0	$90.9	$102.9
Comprehensive Hemophilia Treatment Centers	$192.1	$29.6	$33.5
All other	$284.6	$29.7	$33.6
Subtotal	$5,742.9	$599.3	$678.4
Total	**$43,912.4**	**$4,582.2**	**$5,187.6**

Sources: Drug Channels, HRSA Office of Pharmacy Affairs

An Important benefit of the 340B program to covered entities is their ability to retain the value of the discounts from the list prices for prescribed medications. For example, if the list price of a drug is

$100 and the rate of discount is 53 percent, as shown in Exhibit 2, then the value of the discounted purchase is $47. The value of the discount is $53, which the legislation creating the 340B program intends that covered entities use to strengthen the healthcare safety net by stretching federal resources as far as possible so that they can reach more eligible patients and provide more comprehensive services. The diminished value of discounts is estimated at almost $5.2 billion or 11.8 percent of all 340B program purchases in 2021. This $5.2 billion represents lost revenue to covered entities and would almost certainly have a significant impact on the operating budgets of covered entities and their individual and collective ability to support healthcare safety nets.

Another potential revenue loss associated with the loss of patients for these covered entities would be insurance coverage and other revenue. Based on the assessment of this potential impact on health centers, it is highly likely that this loss of revenue would be several times greater than the value of the discounts on 340B program purchases. In other words, the loss of 340B discounts also results in a loss of patient volume and associated revenues. The estimated loss of revenue from discounts on 340B program purchases is in the range of $5.2 billion. The loss of revenue from insurance and other patient derived sources would likely be in the tens of billions of dollars.

IMPACTS ON PHARMACEUTICAL COMPANIES

Impacts of 340B program modifications on pharmaceutical companies can be measured in terms of the $4.6 billion in reduced value of purchases. This reduction would occur in the context of the Medicaid Drug Rebate Program, which also provides reduced prices for prescription medications. In 2021, total spending on discounted 340B program purchases and net spending through the Medicaid Drug Rebate Program totaled $82 billion. If 340B program purchases were reduced by $4.6 billion, this would amount to 5.6 percent of the total spending of both programs as reflected in Exhibit 14.

Exhibit 14: Impact of Reduced Purchases on Pharmaceutical Companies

Categories of drug spending	Value ($ billions)
Discounted purchases through 340B program	$43.9
Net spending through Medicaid Drug Rebate Program	$38.1
Total 340B and Medicaid	$82.0
Potential reduction in 340B program discount purchases	$4.6
Reduced 340B program purchases as share of total 340B and Medicaid drug spending	5.6%

Sources: Drug Channels, HRSA Office of Pharmacy Affairs, Medicaid

In 2019, the pharmaceutical industry reported sales of $360 billion. That year, the 340B Program purchases amounted to 8.3 percent of the industry's total sales.[39] The $4.6 billion in reduced sales

[39] Drug Channels, "New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales," June 9, 2020 https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html

would amount to less than 1.3 percent of total sales for the pharmaceutical industry in 2019. This minimal impact might be reduced if a more restrictive 340B program resulted in more medications being purchased through the Medicaid Drug Rebate Program.

IMPACTS ON TAXPAYERS

Medication can be central and necessary to the health of individuals. The loss of patients' access to prescription medications through the 340B program could result in these patients no longer receiving healthcare services from covered entities since without medication there may no point to ancillary services. One potential consequence of no longer receiving healthcare services would likely be an increase in the use of emergency departments, which are generally obligated to provide care regardless of an individual's ability to pay.

On average, America generates 40.5 emergency department visits annually per 100 people.[40] Community health centers have demonstrated an ability to sharply reduce the rate of emergency department visits by providing care that addresses health needs that might otherwise prompt individuals to go to emergency rooms.

A study conducted by the Government Accountability Office found that health centers were able to reduce the need for emergency department visits by 63 percent to a rate of 15 emergency department visits annually per 100 people.[41] Given that reduction, if patients lose access to ongoing healthcare at health centers, one likely result is an increase in annual emergency department visits of roughly 25.5 visits per 100 people.

Given the estimated loss of patients by health centers, Ryan White HIV/AIDS programs, and hemophilia treatment centers, it is possible to estimate the increase in emergency department visits that will be generated by these former patients. As indicated in Exhibit 15, potentially lost patients could generate more than 2.1 million emergency department visits annually. At an average cost of $570 per visit, these visits would generate total costs exceeding $1.2 billion.[42]

[40] National Center for Health Statistics, "National Hospital Ambulatory Medical Care Survey: 2020 Emergency Department Summary Tables" https://www.cdc.gov/nchs/fastats/emergency-department.htm
[41] Government Accountability Office, "Hospital Emergency Departments: Health Center Strategies That May Help Reduce Their Use," April 11, 2011 https://www.gao.gov/products/gao-11-414r
[42] Weber, Belinda, "Should you go to the emergency room or visit urgent care?" Medical News Today, December 19, 2022 https://www.medicalnewstoday.com/articles/urgent-care-or-emergency-room

Exhibit 15: Potential Impacts on U.S. Emergency Department Visits

Nature of delivery sites	Potential loss of patients	Potential increased ED visits	Value of increased ED visits (millions)
Community health centers	7,523,058	1,919,508	$1,094
Ryan White HIV/AIDS	117,769	30,049	$17
Comprehensive Hemophilia Treatment Centers	6,160	1,572	$1
Total	7,646,987	1,951,129	$1,112

Source: Drug Channels, National Association of Community Health Centers, National Center for Health Statistics

In 2020, government programs were the likely source of payment for 62 percent of emergency department visits. Programs such as Medicaid, Children's Health Insurance Program, or other state-based programs (36.6 percent), Medicare (21.7 percent), or a combination of Medicare and Medicaid (3.8 percent) were the expected payment source for most emergency department visits. Accordingly, restrictions on the 340B program will place more pressure on taxpayers to pay for healthcare.

Sage estimates that government programs would pay for $760 million of the $1.2 billion in costs for increased emergency department visits because of the loss of patients among 340B program covered entities. The bulk of this cost -- $448 million -- would be borne by state-based programs such as Medicaid and the Children's Health Insurance Program. Medicare would pick up $265 million of these added costs while a combination of Medicare and Medicaid would pay the remaining $46 million, as indicated in Exhibit 16.

Exhibit 16: Government Payments for Potential Increase in U.S. Emergency Department Visits

Source of payments	Share of total cost	Cost of increased ED visits ($ millions)
Medicaid, the Children's Health Insurance Program, or other state-based programs	36.6%	$407
Medicare	21.7%	$241
Combination of Medicare and Medicaid	3.8%	$42
All government programs	*62.1%*	*$691*
Non-government share	*37.9%*	*$422*
Total	**100.0%**	**$1,112**

Source: Drug Channels, National Association of Community Health Centers, National Center for Health Statistics

Conclusion

This study assesses the impacts of proposed changes to the 340B program. These changes have been proposed to limit the program's scope. Because of data limitations, Sage's policy impact estimates have primarily focused on impacts on consolidated health center programs and Ryan White HIV/AIDS program grantees.

PRINCIPAL ANALYTICAL FINDINGS

- Were an income limitation of 200 percent of federal poverty level imposed, nearly 3.4 million patients at consolidated health centers and Ryan White programs would lose access to 340B benefits nationally;

- The estimated loss of patients by health centers, Ryan White HIV/AIDS programs, and hemophilia treatment centers would generate an estimated 2.1 million emergency department visits annually across the nation. At an average cost of $570 per visit, these visits would generate total costs exceeding $1.2 billion;

- Based on 2020 data, government programs would finance 62 percent of these additional emergency department visits.

About Sage Policy Group

Sage Policy Group is an economic and policy consulting firm headquartered in Baltimore, MD. Dr. Anirban Basu, Sage's chairman and CEO, founded the firm in 2004. Over a period spanning nearly two decades, Sage has managed to create a client base that encompasses more than forty states and seven countries and includes Fortune 500 companies, NFL teams, aquariums and zoos, state and local governments, insurance companies, banks, brokerage houses, major medical systems, trade organizations, and law firms, among others.

The company is especially well known for its analytical capabilities in economic impact estimation, school enrollment forecasting, economic development, economic forecasting, fiscal impact analyses, legislative analyses, litigation support, environmental economics, and industry outlooks, and has significant experience in the subject areas of construction, healthcare, energy, real estate, manufacturing, professional sports, lotteries, agriculture, tourism, entrepreneurship, government contracting, secondary and post-secondary education, and the economics of retirement. The firm is also known for its superior communications and messaging skills.

In addition to leading Sage, Dr. Basu has emerged as one of the nation's most recognizable economists. He serves as the chief economist to Associated Builders and Contractors and the International Food Distributors Association and as the chief economic adviser to the Construction Financial Management Association. He chaired the Maryland Economic Development Commission from 2014 to 2021 and currently chairs the Baltimore County Economic Advisory Committee. He has been interviewed by CNBC, CNN, Fox Business, Axios, the New York Times, and many others.

Dr. Basu's lectures in economics are delivered to audiences across the U.S. and abroad. In recent years, he has focused upon health economics, the economics of education, and economic development. He has lectured at Johns Hopkins University in micro-, macro-, urban, and international economics, and most recently, global strategy. He is now the Distinguished Economist in Residence at Goucher College, where he teaches History of Economic Thought.