340B Drug Distribution: Prohibition on Discrimination

HB 1056/Ch. 962(2), 2024

Maryland Prescription Drug Affordability Board
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Final Version

MARYLAND
Prescription Drug Affordability Board

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Executive Summary

- There are a few unique aspects to the 340B program in Maryland because of the global budget system set through the Maryland Health Services Cost Review Commission (HSCRC). Most importantly, the Maryland global budgets incorporate 340B acquisition costs in the setting of the global budget.
- Despite efforts to collect data through the 2024 HB1056, Maryland does not have the data necessary to meaningfully analyze the scope, scale, implementation, or impact of the 340B program in Maryland. Maryland will likely need the authority to implement a reporting program to collect meaningful state-level data, similar to what has been done in other states, such as Minnesota. The Maryland PDAB tried to collect the data, but received a very poor response rate

The Maryland Prescription Drug Affordability Board (PDAB) sincerely thanks the 340B covered entities that submitted data for the 340B Data Request, including the 24 340B Entity IDs with 19 parent covered entities and 5 child sites.

This included 3 Disproportionate Share Hospitals (DSH) (3 Parent, 0 Child), 11 Community Health Centers (CHC) (7 Parent, 5 Child), 5 Sexually Transmitted Disease Clinics (STD) (5 Parent, 0 Child), 3 Ryan White Part A (RWI) (3 Parent, 0 Child), and 1 Sole Community Hospital (SCH) (1 parent, 0 child). However, the response rate did not allow for a meaningful understanding of the 340B program in Maryland.

If the state would like to understand the scope and implementation of the program in Maryland, it may be necessary to pass legislation to require the collection of data related to the 340B program, similar to what has been implemented in states like Minnesota.

Introduction

Introduction to the 340B Drug Pricing Program

The 340B Drug Pricing Program, established in 1992, provides discounted drugs to certain safety net health care providers and institutions, known as covered entities. Covered entities are often reimbursed for these discounted drugs at the full commercial price by payors and insurers, which provides an essential revenue stream for many covered entities.

The program has expanded dramatically since its inception. Between 2010 and 2021, 340B purchases by the majority of 340B covered entities that use the Prime Vendor Program (PVP) increased from $6.6 billion in 2010 to $43.9 billion in 2020.[1] Based on most recently available data, annual purchases by 340B covered entities grew by more than 20%, rising from $66.3 billion in 2023[2] to $81.4 billion in 2024.[3]

There are currently no direct federal or state requirements on how covered entities use revenues generated under the 340B program. For many covered entities, these resources are essential for staying in business and serving underserved populations. For other covered entities, the program provides additional revenue that can be used for other investments to serve their patients and communities.

A central disagreement exists between 340B covered entities and 340B pharmaceutical manufacturers regarding the program's purpose, scope, and the use of 340B resources. Was the program created to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"?[4] Or to "stretch scarce federal resources as far as possible to better serve uninsured and underinsured patients"?[5]

As the program has expanded and evolved, there has been increased interest from policy makers to understand the program, and increased tensions between 340B covered entities and pharmaceutical manufacturers on the appropriate scope and administration of the program.

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[1] Congressional Budget Office, Report: Growth in the 340B Drug Pricing Program, https://www.cbo.gov/publication/60661 September 9, 2025.
[2] HRSA Office of Pharmacy Affairs, OPA Program update - October 2024: 2023 340B covered entity purchases, https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases
[3] HRSA Office of Pharmacy Affairs, OPA Program update - December 2025: 2024 340B covered entity purchases, https://www.hrsa.gov/opa/updates/2024-340b-covered-entity-purchases
[4] 340B Health, 340B Drug Pricing Program Overview, https://www.340bhealth.org/members/340b-program/overview
[5] National Pharmaceutical Council, 340B Drug Pricing Program, https://www.npcnow.org/topics/health-spending/340b-drug-pricing-program

Statutory Background of the Report

House Bill 1056, passed by the Maryland General Assembly in the 2024 legislative session, prohibits pharmaceutical manufacturers from taking certain actions to limit or restrict the acquisition or delivery of a 340B drug. It also requires the Maryland Prescription Drug Affordability Board (PDAB) to study and report findings on the 340B Program.

Specifically, the PDAB, in consultation with the Maryland Department of Health, is required to conduct a study on:

> (1) the current implementation and scope of the 340B Program in the State;
> (2) the implementation and impact of the implementation of Section 1 of the same Act; and,
> (3) the finances of the Program in the State, including how covered entities reinvest savings realized from the Program.

HB1056 authorized the PDAB to require covered entities and 340B manufacturers to report information as necessary to complete the study. Additionally, the PDAB is required to report its findings and recommendations from the study to the Senate Finance Committee and the House Health and Government Operations Committee on or before July 1, 2026.

This report presents the PDAB's findings and recommendations to fulfill the above requirements and serves as a 340B Program resource for policymakers, stakeholders, and Maryland residents.

To gather more information on the scope and finances of the 340B program in the State, the PDAB issued a Data Request to all covered entities in the state.

Current Implementation and Scope of the 340B Program

340B Drug Pricing Program Background

History

Under the Omnibus Budget Reconciliation Act of 1990, a couple of years before the 340B Drug Pricing Program was created, Congress established the Medicaid Drug Rebate Program (MDRP).[6,7] The MDRP, authorized by Section 1927 of the Social Security Act, requires drug manufacturers to provide outpatient drug rebates to state Medicaid agencies, providing them with the "best price" in the market, in exchange for drug coverage.[8,9] States have some authority to impose certain controls, including prior authorization tools, preferred drug lists, and limits on quantity, without violating the rebate agreements.[10]

Impetus

To determine the "best price," the MDRP considered voluntary manufacturer's drug discounts provided to public hospitals and community health clinics. To avoid having to offer these deep discounts to Medicaid programs, manufacturers stopped offering the voluntary discounts to hospitals and clinics, leading to dramatic price increases for these health centers. To mitigate such unintentional consequences and reinstate drug discounts for health centers, Congress followed up by implementing the 340B Drug Pricing Program in 1992.

Creation

Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585) added section 340B to the Public Health Service Act (42 U.S.C. § 256b), thereby establishing the 340B Drug Pricing

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[6] H.R.5835 - Omnibus Budget Reconciliation Act of 1990 Summary, https://www.congress.gov/bill/101st-congress/house-bill/5835

[7] H.R.5835 - Omnibus Budget Reconciliation Act of 1990 Text, https://www.congress.gov/bill/101st-congress/house-bill/5835/text

[8] Social Security Act, Compilation of the Social Security Laws, Payment for Covered outpatient Drugs, https://www.ssa.gov/OP_Home/ssact/title19/1927.htm

[9] Medicaid, Medicaid Drug Rebate Program, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program

[10] Medicaid and CHIP Payment and Access Commission, Prescription Drugs, https://www.macpac.gov/topic/prescription-drugs/#:~:text=Under%20the%20Medicaid%20Drug%20Rebate,prior%20authorization%2C%20and%20quantity%20limits.

Program ("340B Program"). The 340B Program requires pharmaceutical manufacturers to enter pharmaceutical pricing agreements with the Secretary of the Department of Health and Human Services (HHS) in exchange for Medicaid and Medicare drug coverage. This program enables certain health care entities that serve low-income and uninsured patients to purchase outpatient drugs at discounted costs. According to the Health Resources and Services Administration (HRSA), the agency that administers the program, "[t]he 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[11]

Expansion

The 340B Program has expanded and changed multiple times since its inception. In 2010, the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) expanded the list of covered health care entities that are eligible to participate in the program to include children's hospitals, cancer treatment facilities, critical access hospitals, rural referral centers, and sole community hospitals that have a certain high volume of low-income or uninsured patients (Disproportionate Share Hospital, or DSH, percentage). Among other things, the ACA also allowed covered entities to contract with an unlimited number of retail "contract pharmacies" to dispense 340B drugs to eligible patients.

[11] HRSA, 340B Drug Pricing Program, https://www.hrsa.gov/opa

Current Implementation of the Program in Maryland

Types of 340B Program Covered Entities and Patient Eligibility

340B Covered Entities

Section 340B(a)(4) of the Public Health Service Act lists the different types of covered entities that can participate in the 340B Program. These entities can be grouped into four main categories: (1) Federally qualified health centers (FQHCs); (2) Ryan White HIV/AIDS Program Grantees; (3) Hospitals; and (4) Specialized clinics. The HRSA 340B Drug Pricing Program Eligibility website contains detailed information on qualification.[12] Entities must recertify their eligibility each year.

1. Federally Qualified Health Centers (FQHCs)
    a. Health Center Program Award Recipients
    b. Health Center Program Look-Alikes
    c. Native Hawaiian Health Centers
    d. Tribal and Urban Indian Health Centers
2. Ryan White HIV/AIDS Program Grantees
    a. Ryan White HIV/AIDS Program Grantees
3. Hospitals
    a. Children's Hospitals
    b. Critical Access Hospitals
    c. Disproportionate Share Hospitals
    d. Free Standing Cancer Hospitals
    e. Rural Referral Centers
    f. Sole Community Hospitals
4. Specialized clinics
    a. Black Lung Clinics
    b. Comprehensive Hemophilia Diagnostic Treatment Centers
    c. Title X Family Planning Clinics
    d. Sexually Transmitted Disease Clinics
    e. Tuberculosis Clinics

Contract Pharmacies

A 340B contract pharmacy is an outside commercial pharmacy (like CVS, Walgreens, or a local independent pharmacy) that enters into a formal legal agreement with a 340B covered entity to dispense discounted drugs to that entity's patients.[13]

[12]HRSA, 340B Eligibility, https://www.hrsa.gov/opa/eligibility-and-registration
[13] HRSA, 340B Contract Pharmacy Services, https://www.hrsa.gov/opa/implementation-contract

Contract pharmacies provide an essential role because many covered entities do not have in-house pharmacies.[14] Until 2010, HRSA guidance generally permitted one contract pharmacy per covered entity.[15] However, in 2010, HRSA advised that covered entities could contract with an unlimited number of contract pharmacies.[16] As a result, the number of contract pharmacies working with covered entities increased from approximately 1000 in 2010 to almost 28 000 in 2021.[17]

340B Eligible Patients and Claims

For a claim to be 340B-eligible, the following elements are required, among others:

1. The drug must be an outpatient prescription drug;
2. The patient for whom the drug is dispensed or administered must be an established patient of a 340B covered entity (above);
3. That covered entity must maintain health records documenting the specific patient's care;
4. The patient must receive services from an employee of the covered entity or individual covered by another valid contract/arrangement; and,
5. If dispensed, the drug must be dispensed by a covered entity's in-house retail pharmacy or a contract pharmacy (operating under a specific 340B contract with a covered entity).

Maryland-Specific 340B Program Details

In 2010, Maryland pioneered the establishment of a hospital global budgeting program that was expanded to all of the state's general acute care hospitals in 2014. This Global Budget Revenue (GBR) methodology, administered by the Health Services Cost Review Commission (HSCRC), was integral to its All-Payer Model goals of promoting better care, better health, and lower costs for all Maryland Patients.

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[14] Knox RP, Wang J, Feldman WB, Kesselheim AS, Sarpatwari A. Outcomes of the 340B Drug Pricing Program: A Scoping Review. JAMA Health Forum. 2023;4(11):e233716. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2812107

[15] US Health Resources & Services Administration. Notice regarding section 602 of the Veterans Health Care Act of 1992; contract pharmacy services. Fed Regist. 1996;61(165):43549-43556. https://www.govinfo.gov/content/pkg/FR-1996-08-23/pdf/96-21485.pdf

[16] US Health Resources & Services Administration. Notice regarding 340B Drug Pricing Program—contract pharmacy services. Fed Regist. 2010;75(43):10272-10279. https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf

[17] Mulligan K. The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments. University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics. Published October 14, 2021, https://schaeffer.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments

Under this framework, each hospital's total annual revenue is set at the beginning of each fiscal year, based on historical data in combination with factors including but not limited to inflation, population-driven volume increases, and shifts in market share.

Due to global budget constraints, Maryland's 340B program operates uniquely compared to the rest of the country. The total annual revenue accounts for 340B acquisition costs, and therefore hospitals have very limited ability to generate 340B spread compared to those in other states. As a result, hospital incentives are uniquely focused on reducing costs and improving outcomes. One detail to note is that the scope of JSCRC review is limited to the discounted drugs that meet the criteria for inclusion in the annual CDS-A surveys. The approximate discount of 40% off Average Sales Price represents an average for those drugs; it is not a weighted average. The drugs that meet the criteria change every year due to the economic dynamics of the drug marketplace. While the potential to use 340B to generate revenue has been highlighted as a national issue, Maryland hospitals do not share such incentives as those in other states may.

At least half of the hospitals in Maryland are 340B covered entities. While there is no single place to get values on 340B spread per drug, and hospitals use different distribution channels that may have different values, the approximate overall 340B discount in the state is 40%. Maryland keeps a list of drugs that are exempt from the global budget; these are volume-variable, but paid. If a drug is not on the exemption list, then it is part of the global budget.

Of note, Maryland is excluded from many federal 340B studies because of the unique global budget model. As a result, many findings and conclusions on a national scale are not as relevant and should not be utilized to make conclusions or policy recommendations for Maryland's 340B program.

Finally, there is a federal trend to move towards changing the 340B program so that the discount may not be front loaded, but rather back loaded through rebates, with hospitals reporting usage and applying for refunds.

The Centers for Medicare and Medicaid Services (CMS) is introducing a new model, States Advancing All-Payer Health Equity Approaches and Development (AHEAD), which seeks to expand global budgeting to more states. Maryland has applied to CMS to transition to the AHEAD model beginning as soon as 2026.

Despite substantial data and understanding of the impact of the 340B program on the Maryland global budget models, there are still substantial gaps in the data for 340B drugs that are filled in the outpatient setting, outside of the global budget.

Current Scope of the 340B Program

National Scope and Trends in the 340B Program

Overview

The 340B Drug Pricing Program is one of the largest drug spending programs in the United States and continues to experience substantial growth over time due to increased participation by covered entities and pharmacies. In 2023, 340B sales of covered outpatient drugs reached $66.3 billion, a 24% increase from $53.7 billion in the prior year of 2022.[18,19]

Despite its size, the 340B Program is not very well understood, and particularly little is known about its revenue and how these revenues are used or regulated. This report thus sets out to understand: 1) how is spending reported and how accurate are these spending estimates, 2) what are entities allowed to spend on, and 3) what trends have there been in spending over time.

Data Sources

Total spending of 340B is reported annually by the Health Resources and Service Administration (HRSA), which administers the overall program.[20] Spending for each of the covered entity types is aggregated for all entities across the nation and reported alongside information on total spending for each of the top 10 branded drugs in the same year. However, the data for this report is not collected by HRSA directly from covered entities. Rather, it is captured by Apexus, a privately-owned company, that has contracted with HRSA to be the Prime Vendor, supporting 340B stakeholders by providing technical assistance, educational programs, and compliance resources; negotiating contracts between manufacturers, distributors, and covered entities; and ensuring access through a nationwide distribution network.[21] The Prime Vendor tracks all transactions through an electronic platform, where entities submit details for all purchase orders including drug name, quantity, price, date of purchase, and date of receipt.[22] Some sources note that drug spending is reported based on discounted prices, with an average discount rate of 57%

[18] HRSA, 2023 340B Covered Entity Purchases, https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases
[19] HRSA, 2022 340B Covered Entity Purchases, https://www.hrsa.gov/opa/updates/2022-340b-covered-entity-purchases
[20] HRSA, 2023 340B Covered Entity Purchases, https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases
[21] Apexus, The 340B Prime Vendor Program, https://www.apexus.com/340b-prime-vendor-program
[22] Apexus, 340B Compliance Tools and PVP Resources, https://www.340bpvp.com/resource-center/340b-tools

of list price.[23] When measured with the wholesale acquisition cost of drugs, one group estimates 340B sales actually may total $126.3 billion in 2022.[24]

HRSA administers and oversees covered entities' compliance with 340B Program requirements through annual audits, among other efforts. If audits identify noncompliance with program requirements, HRSA issues findings to covered entities and requires them to take corrective action to continue participating in the 340B Program. HRSA conducts 200 audits each year for nearly 13,000 covered entities. According to a report by GAO, more than half of programs were found to be noncompliant in audits conducted between 2012-2019.[25]

This system raises potential concerns for accuracy of reporting. Due to the limited oversight of the Prime Vendor Program, the level of compliance as well as the accuracy and timeliness of data for a majority of 340B entities remain uncertain. Reporting only aggregated data limits the ability of others to analyze and understand a major aspect of the healthcare ecosystem.

Moreover, because HRSA reporting is limited to the Prime Vendor Program, data is not reported for the approximately 10% of 340B facilities that do not use the Prime Vendor.[26] Spending reports are thus underestimating true spending of the program. Industry insiders, watchdog agencies, and academic researchers have cross-referenced OPAIS data with external resources such as all-payer claims data to adjust the spending reported by HRSA and give an alternate estimate of federal spending on the program.

Trends in the 340B Program

Overall, spending for the 340B program has increased throughout the years, with a more rapidly increasing rate of change starting in the 2010s (Table 1). Spending in the most recent years of data show an increase of 23.5%, 22.3%, and 15.6% from the year immediately prior, with increases likely to continue in coming years. Regarding the magnitude of these numbers, this translates to an over $54 billion increase in the eight years of reporting since 2015, much higher than the $8.1 billion increase in the eight years prior to 2015.[27]

[23] PhRMA, 340B spending is exploding, forcing prices up for patients, employers and government programs, https://phrma.org/blog/340b-spending-is-exploding-forcing-prices-up-for-patients-employers-and-government-programs

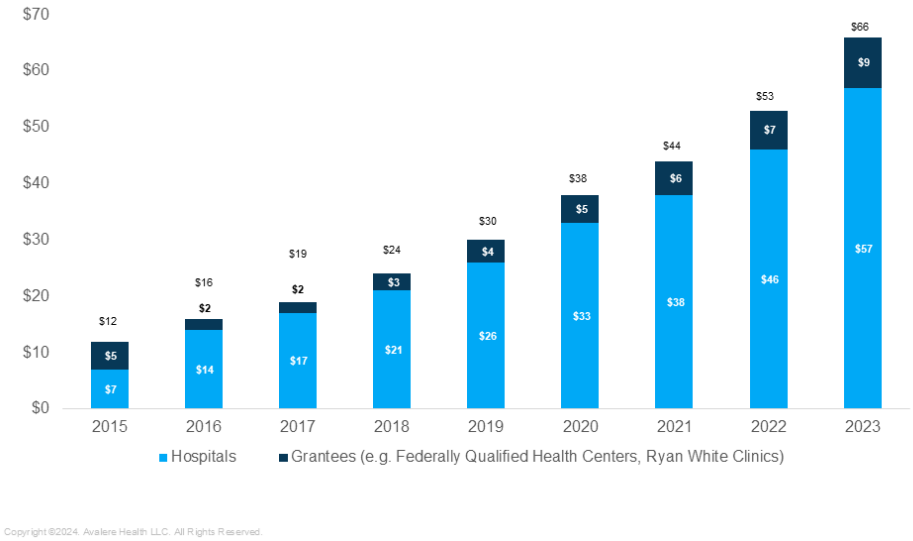
[24] BRG, Measuring the Relative Size of the 340B Program: 2022 Update, https://www.thinkbrg.com/insights/publications/measuring-relative-size-of-340b-program-2022-update/

[25] GAO, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, https://www.gao.gov/products/gao-21-107

[26] *Id.*

[27] Kaiser Family Foundation, Key Facts About Hospitals, https://www.kff.org/key-facts-about-hospitals/?entry=hospital-finances-340b-drug-pricing-program

Table 1: 340B Drug Sales from 2015-2023 (Billions)[28]



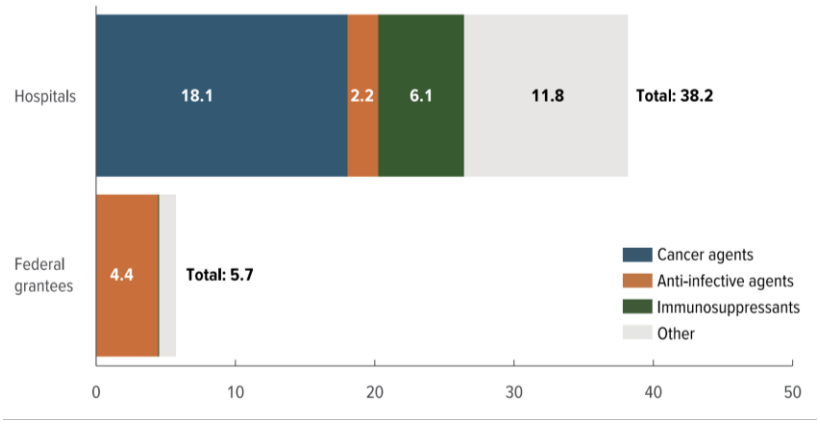
Note: Data reflect purchases through the 340B Prime Vendor Program; total 340B purchases may be higher.

This increase in spending seems to be driven primarily by hospital-based facilities. In the last three years of data, hospital-based facilities (including disproportionate share hospitals, children's hospitals, rural hospitals, free standing cancer centers, and affiliated child sites), have accounted for the largest portion of spending, comprising 87% of total expenditures annually. In comparison, federal grantees (including federally qualified health centers, Ryan White clinics, family planning clinics, tuberculosis clinics, and more) have represented just 13% of overall spending.[29]

Moreover, the growing expenditure has become increasingly concentrated within specific drug classes. In 2021, the largest share of spending was directed toward cancer agents ($18.1 billion), followed by anti-infective agents ($6.6B) and immunosuppressants ($6.2B)[30]. Together, these three classes of drugs made up more than 70% of all 340B spending that year. Notably, cancer agents were the largest source of hospital-based spending, accounting for 47.3%, while anti-infective agents were the largest source of federal grantee spending at 77.2% (Table 2).

[28] Avalere, October 24, 2024, 340B Purchase Data Highlights Continued Program Growth, https://avalere.com/insights/340b-purchase-data-highlights-continued-program-growth
[29] CBO, Growth in the 340B Drug Pricing Program, September 2025, https://www.cbo.gov/publication/61730
[30] GAO, Spending in the 340B Drug Pricing Program, 2010 to 2021, https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf

Table 2: 340B Spending, by Facility Type and Drug Class, 2021 (Billions)[31]



A closer look at individual drugs reveals that the top ten 340B drugs alone accounted for nearly one third of all 340B spending, amounting to $21.8B of the $66.3B in total expenditures (Table 3). When compared to the most recent Medicare spending data, 340B spending for these drugs was nearly 20% higher. Although more recent data is unavailable, a GAO analysis from 2012 found that per beneficiary spending for Medicare Part B drugs was higher at 340B DSH hospitals ($144) than non-340B hospitals ($60).[32] Given together, these findings have suggested to policymakers that the 340B program may provide incentives for entities to either prescribe more drugs or more costly medications. However, more recent studies have weakened these claims. When controlling for patient-level risk factors (age, comorbidities, income, etc.) as well as hospital-level risk factors (teaching status, geography, number of beds, etc.), studies have shown that there is no meaningful difference in spending between 340B and non-340B hospitals.[33,34]

[31] GAO, Spending in the 340B Drug Pricing Program, 2010 to 2021, https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf

[32] GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, https://www.gao.gov/products/gao-15-442

[33] Li Y, Xu S, Association of Beneficiary-Level Risk Factors and Hospital-Level Characteristics With Medicare Part B Drug Spending Differences Between 340B and Non-340B Hospitals, doi:10.1001/jamanetworkopen.2022.0045, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789170

[34] Dickson S, James K, Comparison of Generic Prescribing Patterns Among 340B-Eligible and Non-340B Prescribers in the Medicare Part D Program, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804988#:~:text=Overall%2C%2086.6%25%20of%202020%20Part,%25%20among%20non%2D340B%20prescribers.

Table 3: 2023 340B Sales Compared to 2022 Medicare Spending for Top 10 340B Drugs[35]

Brand Name	Primary Indication	2023 Total 340B Sales	2022 Total Medicare Part B + D Spending
Keytruda	Oncology	$6,905,377,755	$5,027,119,004
Biktarvy	HIV	$3,577,083,273	$2,703,581,195
Opdivo	Oncology	$1,953,824,181	$1,893,787,032
Darzalex Faspro	Oncology	$1,891,559,523	$1,618,324,049
Ocrevus	Oncology	$1,850,213,455	$816,698,392
Trikafta	Cystic Fibrosis	$1,817,226,143	$646,868,282
Humira (CF) Pen	Immunology	$998,809,804	$3,694,000,753
Descovy	HIV	$969,510,516	$574,036,753
Entyvio	Immunology	$949,744,300	$749,730,440
Durvalumab	Oncology	$889,594,527	$575,101,380
Total		$21,802,943,477	$18,299,247,129

The growth in spending is also influenced by changes in dispensing methods. Prior to 2010, 340B covered entities could only dispense drugs through their in-house pharmacies. However, starting in 2010, these entities were permitted to contract with multiple external pharmacies, expanding access to outpatient drugs. This shift led to a dramatic increase in program participation, with the number of retail pharmacies involved growing from 601 in 2009 to nearly 27,000 by 2022. Today, large commercial pharmacy chains such as CVS, Walgreens, Walmart, and Rite Aid dominate this network, collectively accounting for 78% of all contracts.[36]

Data from the HRSA reveals that 19.6% of the growth in spending from 2010 to 2021 can be attributed to drugs dispensed at these contracted pharmacies. It's important to note that while the expanded dispensing network is reflected in the increased overall spending, these pharmacies incur additional costs within the system. Although payment structures are unclear, contract pharmacies typically charge dispensing fees per drug or a share of total revenues from the 340B entity, leading to increased healthcare costs overall.[37]

Overall, the data available for these national trends is not comprehensive or robust. All of the prior data is based on a few aggregate numbers released by HRSA each year or data from OPAIS cross-referenced with external resources such as all-payer claims. There are substantial opportunities for transparency to better understand the national scope of the program

[35] Avalere Health, 340B Purchase Data Highlights Continued Program Growth, https://avalere.com/insights/340b-purchase-data-highlights-continued-program-growth

[36] McGlave C, Bruno JP, Watts E, Nikpay S. 340B Contract pharmacy growth by pharmacy ownership: 2009-2022. Health Aff Sch. 2023;2(1):qxad075. https://academic.oup.com/healthaffairsscholar/article/2/1/qxad075/7465208

[37] GAO, Drug Discount Program - Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, https://www.gao.gov/assets/gao-18-480.pdf

State-Level Scope of the 340B Program

Introduction

While information about the 340B Program at the national level is generally opaque and incomplete, information about the 340B Program at the state level is almost non-existent. HRSA provides data to calculate descriptive metrics on the number and types of covered entities in the state (discussed below). However, there is almost no information or data available to estimate the scope of the utilization and expenditures in the state.

State Efforts to Understand the State-Level Scope of the 340B Program

State legislatures have been looking into ways to increase transparency of the system by implementing reporting requirements. Minnesota was the first state to do so, requiring covered entities to report acquisition costs, payments received, number of units dispensed or administered, and payments made to contract pharmacies or other non-covered entity parties starting in 2023.[38] As Maine has passed similar legislation, and as other states including Washington are looking to follow in their footsteps, it will be important to understand how conclusions from Minnesota's report reflect national trends.[39]

The Minnesota Department of Health (MDH) released the first Covered Entity Report to the Legislature in November, 2024[40] and the Covered Entity Report to the Legislature in November, 2024 (2026).[41] These reports have provided novel insights into spending and transactions under the program, especially at the state-level.

The first report was based on 2023 data and only included dispensed drugs. The first report excluded physician-administered drugs, which likely make up over half of 340B expenditures. The first report found that Minnesota covered entities collected $1.5 billion in reimbursements for 340B drugs purchased at $734 million dollars, generating $766 million in gross 340B revenue. After accounting for $120 million in payments made to outside parties for administering the program, net 340B revenue was approximately $630 million.[42]

The second report was based on 2024 data and included both dispensed drugs and physician administered drugs. The second report found that Minnesota covered entities collected $3.05

[38] 2025 Minnesota Statutes, 62J.461 340B Covered Entity Report, https://www.revisor.mn.gov/statutes/cite/62J.461
[39] Maine Revised Statutes, §1728. Prescription drug transparency report, https://legislature.maine.gov/statutes/22/title22sec1728.html
[40] Minnesota Department of Health, 340B Covered Entity Report, 2024, https://www.health.state.mn.us/data/340b/docs/2024report.pdf
[41] Minnesota Department of Health, 340B Covered Entity Report, 2026, https://www.health.state.mn.us/data/340b/docs/2025report.pdf
[42] Minnesota Department of Health, 340B Covered Entity Report, 2024, https://www.health.state.mn.us/data/340b/docs/2024report.pdf

billion in reimbursements for 340B drugs purchased at a cost of $1.53 billion. After accounting for $165 million in administrative costs, the report estimates a total net revenue of $1.34 billion for Minnesota covered entities. This confirmed that physician-administered drugs make up over 50% of the 340B revenues. Both reports showed the majority 340B net revenue was generated by hospitals (95.5 percent in 2023 vs. 97.6 percent in 2024), and among hospitals, those qualifying under the disproportionate share hospital designation generated the most (78.9 percent relative to 10.5 percent among CAHs and 8.2 percent among other hospitals in 2024).[43]

These reports have also identified challenges and opportunities for states as they try to collect these data.[44]

Maryland Scope of the 340B Program

Introduction

Similar to other states, there is very little Maryland-specific information available to understand the state-level scope of the 340B program. HB1056 authorized the PDAB to require covered entities and 340B manufacturers to report information as necessary to complete the study. The PDAB completed a data request (data request with results discussed below).

Maryland Data Sources and Availability

The PDAB explored different opportunities to access and use data to respond to the research questions required in this report, including using proprietary data sources or using claims-data to estimate the scope of the program. However, there were no data to meaningfully answer the research questions.

The PDAB used data from the HRSA Covered Entity Database[45] for descriptive metrics on the number and types of covered entities in the state.

Due to the lack of other available revenue and utilization data, the PDAB conducted a Data Request to all Maryland covered entities with the option for 340B manufacturers to submit. The details of the data request are described in Appendix A.

[43] Nickpay S, Reinke M, Mcglave C, Health Affairs, Insights From Year Two Of Minnesota's 340B Transparency Report: Lessons For States, https://www.healthaffairs.org/content/forefront/insights-year-two-minnesota-s-340b-transparency-report-lessons-states
[44] *Id.*
[45] HRSA Covered Entity Database, https://340bopais.hrsa.gov/SearchCe

Descriptive Metrics and Trends on Maryland 340B Covered Entities

As of 2026, Maryland has 185 Parent covered entities, 289 covered entity child sites, and 1702 contract pharmacy contracts.

Table 4 shows the types of parent covered entity sites in Maryland. The chart shows that STD Clinics at 29.2% and Family Planning at 24.3% account for over half of the total distribution. Other notable categories include Tuberculosis Clinics at 13.5%, Disproportionate Share Hospitals at 12.4%, and Community Health Centers at 10.8%. Smaller shares are held by Ryan White Clinics at (7.6%), Sole Community Hospitals at (1.1%), Pediatric Hospitals at (0.6%), and Hemophilia Centers at (0.5%).

The data reveals that the majority of active parent entities are concentrated in specialized public health services, with STD Clinics and Family Planning facilities making up more than 53% of the total. This may be driven by policies that incentivize these types of facilities to register as parent sites.

Table 4. Number and Percentage of Covered Entity Types

Parent Covered Entity Type	Number of Entities	Percentage (%)
STD Clinic	54	29.20
Family Planning	45	24.30%
Tuberculosis Clinic	25	13.50%
Disproportionate Share Hospital	23	12.40%
Community Health Center	20	10.80%
Ryan White Clinic	14	7.60%
Sole Community Hospital	2	1.10%
Pediatric Hospital	1	0.60%
Hemophilia Center	1	0.50%

Figure 1 shows the trends in covered entity parent types over time. The longitudinal data shows a period of relatively stable growth followed by a rapid acceleration in 340B registrations starting in 2020, with STD Clinics and Family Planning entities emerging as the primary drivers of recent expansion.

The graph reveals a significant surge in registrations beginning around 2020. STD Clinics (teal line) and Family Planning (pink line) show the most aggressive recent growth, both rising sharply to surpass 40 entities by 2026. Community Health Centers and Disproportionate Share Hospitals show steady, moderate increases, while Tuberculosis Clinics have plateaued at approximately 25 entities since 2008. Pediatric Hospitals, Hemophilia Centers, and Sole Community Hospitals maintain the lowest counts, remaining near zero throughout the period.

Figure 1. Trends in Covered Entity Types Over Time, 1992 to 2026

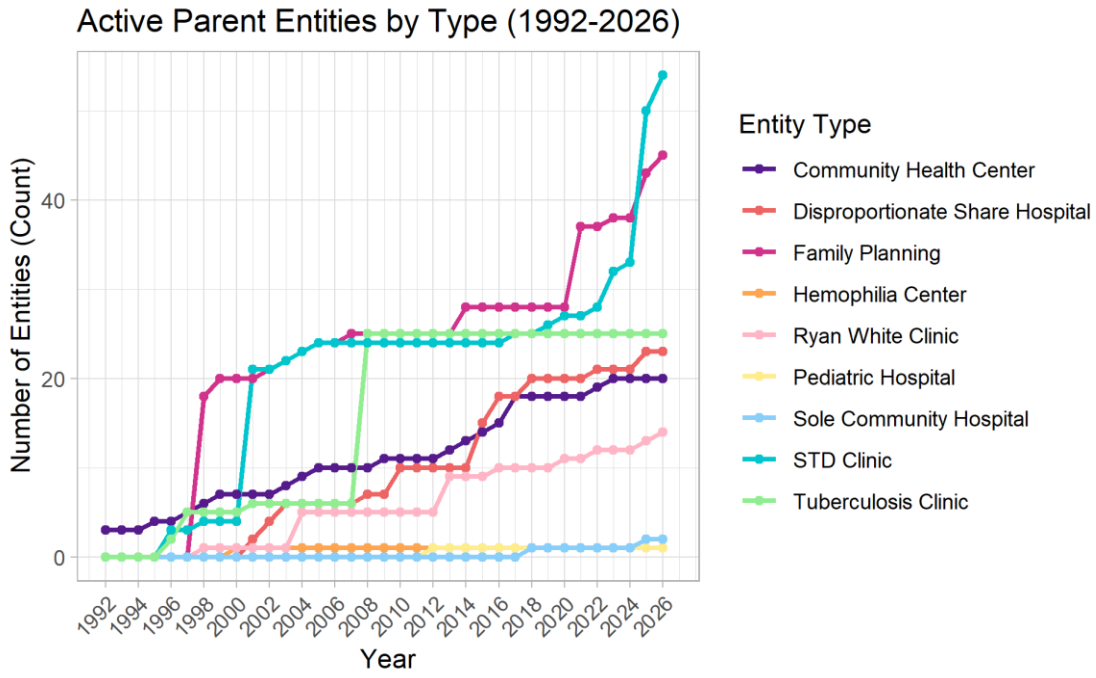


Table 4 and Figure 2 show the changes in the numbers of parent and child sites over time. While parent sites have maintained a path of consistent, predictable growth over the decades, the 340B landscape has shown more volatility with child sites, which saw a decade of rapid expansion followed by a significant contraction.

Parent sites show a steady, consistent upward trend, growing from near zero in 1992 to approximately 185 by 2026. Child sites follow a similar gradual path until 2012, when they experience an explosive surge, peaking at nearly 500 sites around 2021. However, the child sites show a dramatic, sharp decline starting in 2022, dropping to approximately 280 before slightly stabilizing through 2026.

Table 4. Number of Parent and Child Sites Over Time, 2026 to 1992

Year	Parent Entities	Child Sites	Year	Parent Entities	Child Sites	Year	Parent Entities	Child Sites
2026	185	289	**2013**	107	298	**2000**	38	15
2025	178	306	**2012**	102	65	**1999**	37	15
2024	152	288	**2011**	101	61	**1998**	34	12
2023	151	289	**2010**	101	60	**1997**	13	7
2022	145	281	**2009**	98	56	**1996**	9	6
2021	141	493	**2008**	97	49	**1995**	4	5
2020	132	491	**2007**	77	46	**1994**	3	5
2019	130	467	**2006**	76	40	**1993**	3	5
2018	129	474	**2005**	76	38	**1992**	3	5
2017	126	469	**2004**	73	28			
2016	122	429	**2003**	66	20			
2015	117	386	**2002**	61	19			
2014	111	366	**2001**	58	15			

Figure 2. Parent and Child Sites Over Time, 1992 to 2026

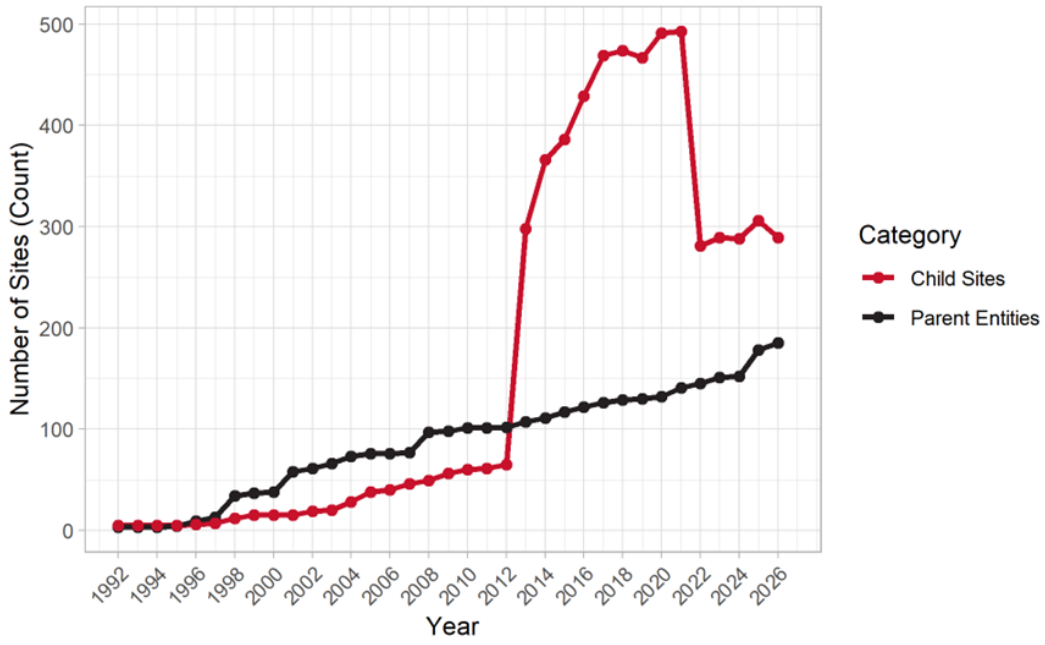
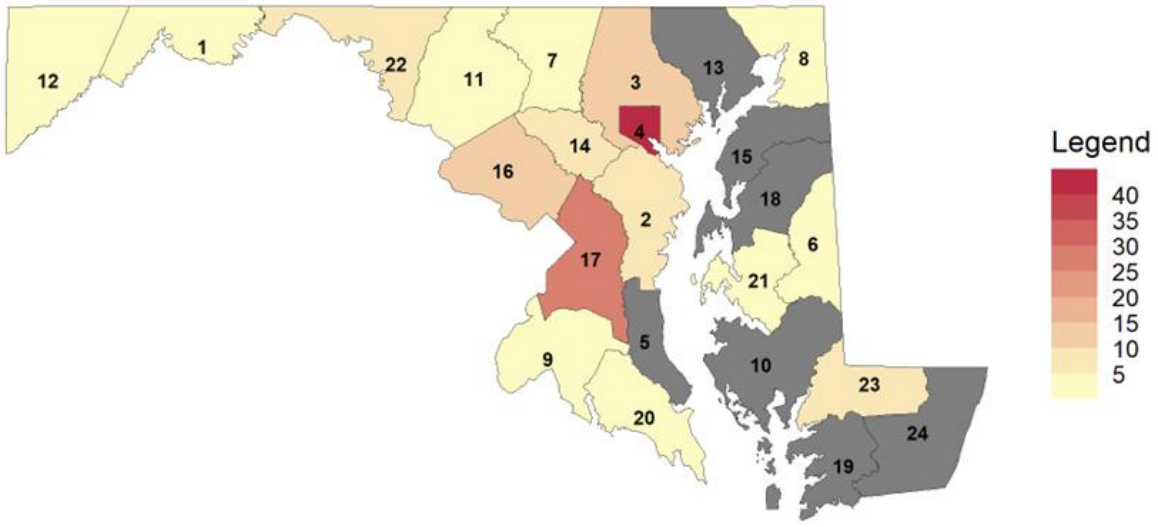


Figure 3 is a heat map that illustrates a significant concentration of parent covered entities within Baltimore City and the Western Counties, highlighting a geographic focus on high-density health service areas. The highest concentrations (darkest shades) are clustered in the central Maryland region, specifically in Baltimore City and the surrounding metro area, as well Prince George's and Montgomery County. Rural western and central-northern counties (i.e., Garrett, Allegany, Carroll, Frederick Counties, etc.) generally show lighter shading, indicating a lower density of parent covered entities. Counties that are grayed out have no recorded covered entities active in the county, most notably those on the Eastern Shore (i.e., Harford, Kent, Queen Anne, Dorchester, Somerset, Worcester Counties).

Figure 3. Heat Map of Covered Entities by Counties in Maryland



Data Source: HRSA 340B OPAIS & Maryland Open Data (2026)

Tables 5 and 6, and Figures 4 and 5 show trends in contract pharmacies. Between 2015 and 2025, the total number of contract pharmacies nearly quadrupled. The most significant trend is the rapid growth of CVS, which moved from a negligible share in 2015 to becoming the market leader by 2025 with 45.2%. Conversely, while Walgreens was the dominant player in 2015 with over half the market (55.5%), its relative share dropped to 24.3% by 2025. Walmart and Rite Aid remained minor participants throughout the decade, with Rite Aid nearly disappearing from the share at 0.7%.

Table 5. Number of Contract Pharmacies in Maryland Over Time, 2026-2000

Year	Count	Year	Count
2026	463	**2013**	72
2025	471	**2012**	33
2024	428	**2011**	18
2023	440	**2010**	13
2022	424	**2008**	8
2021	388	**2007**	7
2020	363	**2006**	7
2019	351	**2005**	6
2018	212	**2004**	6
2017	194	**2003**	3
2016	144	**2002**	2
2015	123	**2001**	1
2014	95	**2000**	1

Figure 4. Trends in Growth of Contract Pharmacies in Maryland, 2000 and 2026

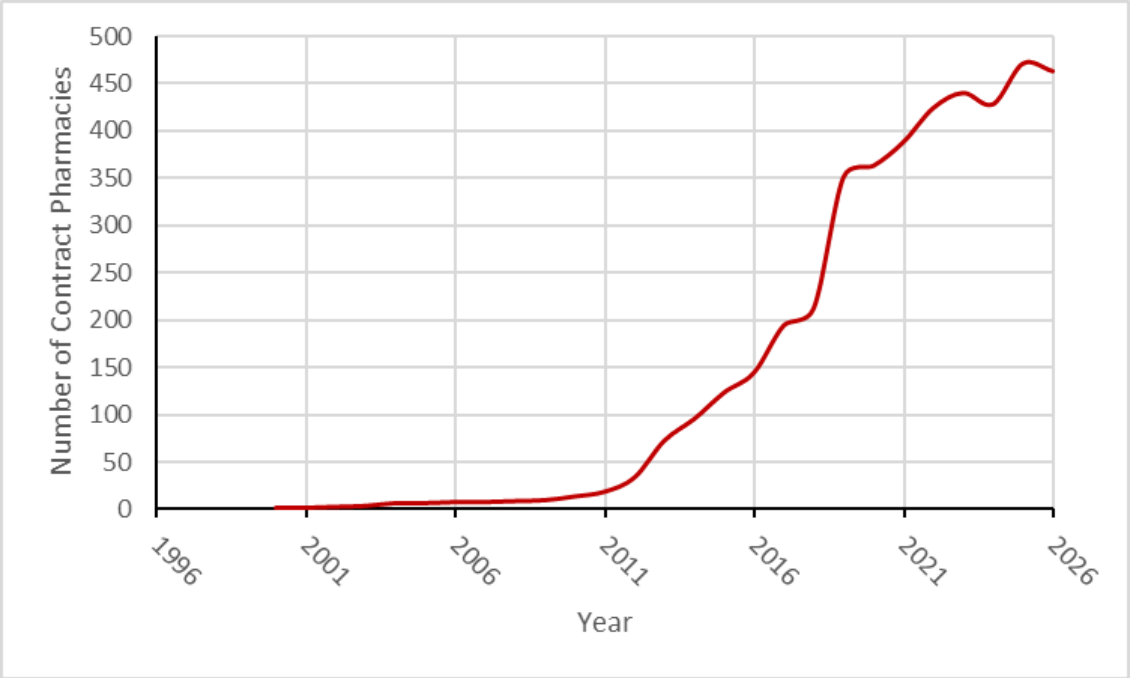
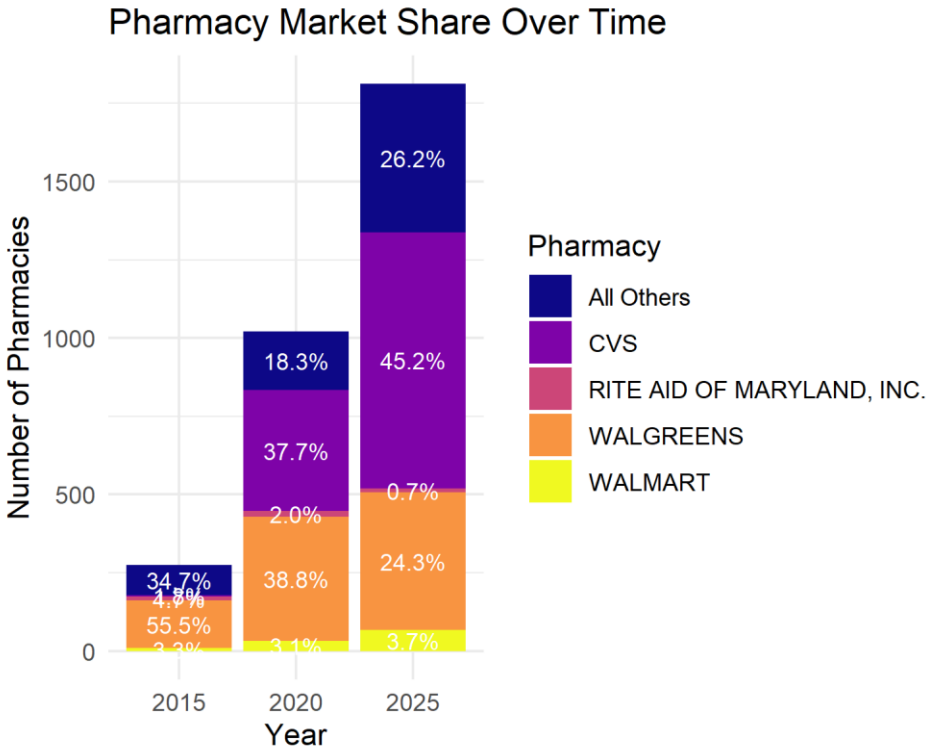


Table 6. Trend in Retail Pharmacy Market Share Over Time in 5-Year Intervals (2015-2025)

Retail Pharmacy	2015	2020	2025
CVS	—	37.70%	45.20%
All Others	34.70%	18.30%	26.20%
Walgreens	55.50%	38.80%	24.30%
Walmart	3.30%	3.10%	3.70%
Rite Aid	4.70%	2.00%	0.70%

Figure 5. Trend in Retail Pharmacy Market Share Over Time in 5-Year Intervals (2015-2025)



Quantitative Metrics and Findings Based on the HB1056 Data Call

The Prescription Drug Affordability Board issued a Data Request to 450 covered entities in the state of Maryland to collect the data necessary to complete this report. The Data Request was posted on Wednesday, March 11, 2026 with a proposed Due Date of Friday, April 10, 2026. At the request of the hospitals and their trade associations, the PDAB extended the Due Date to Monday, June 15, 2026, to increase the response rate from hospitals.

The PDAB received data from 24 340B Entity IDs with 19 parent covered entities (Out of 185) and 6 Child Sites (out of 289) . This included 3 DSH (3 Parent, 0 Child), 11 CHC (7 Parent, 5 Child) , 5 STD (5 Parent, 0 Child), 3 RWI (3 Parent, 0 Child), and 1 SCH (1 parent, 0 child). The PDAB sincerely appreciates the time and effort that covered entities spent responding and submitting to this data request. However, the response rate was so low that Maryland has almost no additional insights to the scope and implementation in Maryland.

The data submitted is summarized below in Table 7.

Table 7. Data from the Covered Entities the Responded to the Data Request[46]

FY	FY25	FY24	FY23
# Covered Entities (Including Child Site)	20	19	17
Total 340B Claims (ct)	2,675,326	2,843,561	2,414,048
Total Reimbursement ($)	$275,172,845	$224,414,563	$197,981,069
Total Acquisition Costs ($)	$164,046,336	$131,533,476	$112,158,615
Spread ($)	$111,114,575	$92,762,474	$85,763,253
Expenses ($)	$32, 636, 191	$26,206,190	$22,794,216
Estimated Savings ($)	$82,819,927	$74,154,081	$72,808,663

[46] In response to the 340B Data Request, the Maryland Hospital Association submitted a letter advising that it was providing data on behalf of 16 hospitals and 2 affiliated on-campus 340B-eligible clinics. To avoid duplication or data redundancy, this data has been excluded from Table 7. The narrative sections in the submission are included in the report below.

Implementation of Section I of 2024 HB1056

In 2024, four civil actions were brought challenging the constitutionality of 2024 Md. Laws ch. 962, § 1 ("H.B. 1056"), Md. Code Ann., Health Occ. § 12-6C-09.1. No stay was agreed to by the parties or ordered by the court, and the law is in effect. In the consolidated action, the district court denied plaintiffs' motions for preliminary injunction. On appeal, the Fourth Circuit Court of Appeals vacated the district court's order and remanded for further proceedings. On May 28, 2026, the Fourth Circuit granted a motion filed by Maryland seeking rehearing en banc. At issue is whether §340B preempts state law regulating the delivery of drugs to contract pharmacies.

The Maryland Board of Pharmacy licenses manufacturers that engage in wholesale distribution of prescription drugs in the state. Under Health Occ. § 12-6C-09.1, a 340B manufacturer may not directly or indirectly deny, discriminate against, or otherwise limit the delivery of a 340B drug to an authorized pharmacy, unless the receipt of 340B drugs is prohibited by the U.S. Department of Health and Human Services, or by the Food Drug and Cosmetic Act.

If the Board of Pharmacy (BoP) receives a complaint against a licensed manufacturer concerning violations of Md. Code Ann., Health Occ. § 12-6C-09.1, it investigates the complaint in accordance with established processes. Alleged violations may be investigated by the BoP or by the Consumer Protection Division of the Office of the Attorney General.

To date, neither the Board of Pharmacy nor the Consumer Protection Division has taken an enforcement action for violations of Md. Code Ann., Health Occ. § 12-6C-09.1.

The Finances of the Program in the State, including How Covered Entities Reinvest Savings Realized from the Program

There are currently no federal guidelines on how covered entities must use revenues from the 340B program, or how covered entities must track and report their use of 340B revenues. Some covered entities voluntarily publish descriptions of how they use and invest their 340B revenues. However, there are no specific standards or requirements around these reports, so it is often difficult to compare or aggregate across entities or meaningfully measure the impact.

Covered Entities Required to Pass Savings on to Patients

Specific groups of 340B entities must pass 340B drug discounts on to low-income or uninsured patients. They are required to do so not by the 340B law, but by the conditions of the federal grants that make them eligible for 340B in the first place.

Federal grantees receive direct funding from the Public Health Service. Their grant covenants require them to provide affordable care and medications to any patient under 200% of the Federal Poverty Level (FPL).

These entities are legally required to use a Sliding Fee Discount Schedule (SFDS), meaning the lower a patient's income, the closer they must get to paying the actual raw 340B cost (or a nominal fee like $5) for their prescription.

The primary entities bound by these rules include:

- Federally Qualified Health Centers (FQHCs)
- Ryan White HIV/AIDS Program Grantees
- Title X Family Planning Clinics
- Other Federal Grantees, such as Tribal/Indian Health Service clinics, black lung clinics, and tuberculosis or sexually transmitted disease (STD) clinics.

This largely leaves the disproportionate share hospitals as the primary type of covered entities that are not required to pass savings on to patients.

National Data on How Covered Entities Reinvest Savings Realized from the Program

The spending of 340B revenue has remained unregulated since the program's inception, leading to general uncertainty about how covered entities allocate their savings.

State-Level Data on How Covered Entities Reinvest Savings Realized from the Program

As states introduce stricter reporting requirements for covered entities, we may soon gain more insight into how these funds are being spent. Although Minnesota's legislation does not mandate reporting on revenue usage, Maine's law specifically aims to track how hospitals utilize 340B savings to support community-based programs and services. [47,48] The Maine report, expected in 2025, may provide the first comprehensive view of how these funds are being allocated across various entities within the state.

Maryland- Level Data on How Covered Entities Reinvest Savings Realized from the Program

Of the 24 covered entities that submitted responses to the data request, 9 responded that they maintain a separate account to track spending of 340B savings.

The Maryland Hospital Association, responding on behalf of multiple unidentified entities, provided examples of how 340B covered entities reinvest savings realized by the programs.[49] The following responses were submitted by Maryland covered entities describing how 340B savings support patient care, community programs, workforce investments, and access to services.

- "As a multi-jurisdictional, nonprofit covered entity serving the broader DMV region, we are deeply invested in our expanding presence across Maryland, where we continue to increase access to care for Maryland residents." Key investments supported by 340B savings include:

[47] Minnesota Statutes 2025, 62J.461 340B Covered Entity Report, https://www.revisor.mn.gov/statutes/cite/62J.461
[48] Maine Revised Statutes, §1728. Prescription drug transparency report, https://legislature.maine.gov/statutes/22/title22sec1728.html
[49] In response to the 340B Data Request, the Maryland Hospital Association submitted a letter advising that it was providing data on behalf of 16 hospitals and 2 affiliated on-campus 340B-eligible clinics. The PDAB includes information from the narratives presented in the letter in this section of the report.

    - Established 25 clinics across Maryland, spanning primary care and specialized services
    - Employ over 5,000 Maryland residents across hospital and clinic locations
    - Partner with the state of Maryland to support care delivery in schools and community settings
- A hospital reported that growing administrative burdens and changes to the 340B program would reduce its ability to reinvest savings into patient care and community support services. Potential impacts identified by the hospital include:
    - Reduced funding for patient support services and hospital-based care programs
    - Impacts to pharmacy staffing, discharge medication assistance, and infusion center operations
    - Reduced financial support for case management, social work, and other patient assistance programs
    - Potential reductions in community services, forcing patients to travel farther or experience gaps in care
    - Challenges maintaining access to specialty medications and services for patients with HIV, cancer, and immunocompromising conditions due to high drug acquisition costs and reimbursement uncertainty
- A hospital reported using 340B savings to support affordable medications, patient assistance programs, transitional care, transportation, behavioral health coordination, housing support, workforce development, and maternal wellness initiatives. The hospital has participated in the 340B program since 2016 and has used savings to expand services, including:
    - Lyft transportation program
    - Peer recovery programs
    - Social determinants of health screenings
    - Congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and oncology clinics

Despite these examples, there is no comprehensive or measurable data on if and how covered entities in Maryland reinvest savings realized from the program.

Conclusion

The 340B Program serves as an essential revenue source for health providers and institutions that provide services to underserved populations. However, despite substantial efforts to research and collect data, the size, scope, implementation, and impact of the 340B Program in Maryland largely remains unknown.

To gain a meaningful understanding of the scope and implementation of the program in Maryland, the state would likely need to implement a reporting program, similar to what has been done in other states, such as Minnesota.

Appendix A: Maryland 340B Data Request

To gather quantitative and qualitative data for this 340B study, PDAB sent out a Data Request to all 340B covered entities in Maryland, with the option for 340B manufacturers to submit data as well. The following items were requested:

A. Fiscal year
B. 340B ID
C. Entity name
D. Total number of 340B claims submitted within the fiscal year (ct)
E. Total annual reimbursement from 340B drugs, equal to the sum of all gross allowed amount payments received from payers for 340B drugs ($)
F. Total annual acquisition cost of 340B drugs, equal to the sum of all net invoice prices paid by entity to purchase 340B drugs after all applicable discounts are applied ($)
G. Total 340B spread, calculated by subtracting total acquisition cost (F) from total reimbursement (E) ($)
H. Total expenses incurred in administration of the 340B program, including payments to contract pharmacies, internal 340B program expenses, and payments to outside vendors and third-party administrators ($)
I. Estimated 340B savings realized when compared to theoretical acquisition of actual 340B drug volume at non-340B prices ($)
J. Total number of in-house pharmacies belonging to the entity
K. In-house outpatient 340B drug volume, in number of claims (340B drug volume passed through in-house pharmacies) ($)
L. Physician-administered 340B drug volume, in number of claims (ct)
M. Total in-house 340B drug volume, in number of claims, equal to the sum of in-house outpatient claims (K) and physician-administered claims (L) (ct)
N. Contract pharmacy 340B drug volume, in number of claims (340B drug volume passed through contract pharmacies) (ct)
O. Total number of contracts between entity and third-party administrators (ct)
P. Does the entity have a separate account for 340B reimbursement? (Yes/No)
Q. Does the entity have a separate account for spending on 340B acquisition? (Yes/No)
R. Does the entity have a separate account for 340B administration costs? (Yes/No)
S. Does the entity have a separate account to track spending of 340B savings? (Yes/No)

To collect contact information for 340B entities in Maryland, PDAB submitted a Freedom of Information Act (FOIA) request to the Health Resources & Services Administration (HRSA). HRSA responded by providing a complete workbook of 340B participants in Maryland as of August 5, 2025. PDAB sent the Data Request to each unique contact email listed, posted the

Data Request on its website, and sent out a GovDelivery email. PDAB Staff also sent the Data Request to additional points of contact if requested or referred from communication with covered entities.

Of the 506 unique Maryland 340B entities listed in HRSA's FOIA response, 455 were classified as "active," 50 were classified as "terminated," and one was classified as "be terminated."

After the Data Request was sent to all 340B covered entities in the state, it was determined that some 340B IDs corresponded to certain health departments for which the data request does not apply.

PDAB received Data Request responses from a total of 24 Maryland 340B Entity IDs.