AIMEDALLIANCE

THE 340B PROGRAM EXPLAINED

Access, Impact, and the Road to Reform

The 340B Drug Pricing Program ("340B Program" or "Program") is a federal program designed to help "covered entities" serving low-income and uninsured patients stretch their financial resources by purchasing prescription drugs at substantially discounted prices.[1] In recent years, the 340B Program has come under scrutiny as certain covered entities, such as hospitals, are expanding the 340B Programs beyond eligible individuals and intended communities.

Health care stakeholders have also expressed concerns that these programs are now serving as mechanisms to increase hospital profitability.[2] Others have flagged that despite 340B increasing hospital profits, these entities aren't providing increased charity care in proportion to their increased profits.[3] Similarly, provider organizations have also raised concern about how large 340B profits are steering patients away from community practices and towards larger, and more expensive, hospital systems. Notably, one oncology association even reported that certain hospitals in Texas were denying health care providers admitting privileges, resulting in oncologists being unable to see and treat their patients when they were admitted to the local hospital.[4]

While there are widespread concerns about the management and oversight of the 340B Program, advocates have struggled to understand the various elements of this program and the reforms that are being proposed. As such, this resource intends to educate stakeholders on the elements of the 340B program and how the various reforms would impact diverse health care stakeholders such as patients, providers, covered entities, and pharmaceutical manufacturers.

Why was the 340B Program created?

The 340B Program was established by Congress in 1992 under Section 340B of the Public Health Service Act to support hospitals and clinics serving vulnerable and underserved populations. The Program requires pharmaceutical manufacturers participating in Medicaid to provide outpatient medications at discounted prices to eligible "covered entities." The goal of this program is to enable these entities to stretch limited federal resources, reduce prescription drug costs, and improve access to care for patients who might otherwise face access and affordability barriers.[5]

How does the 340B Program work?

The 340B Program allows covered entities to purchase outpatient drugs at significantly reduced prices from pharmaceutical manufacturers. These entities can then bill insurers at standard rates, generating savings that can be reinvested in patient care.[6] The Program's discounts help covered entities lower their operating costs, expand services, improve access to medications, and better support uninsured and underinsured patients.[7]

What are 340B ceiling prices and how are they calculated?

The 340B ceiling price is the maximum price that drug manufacturers can charge covered entities for outpatient drugs. It is calculated using a formula based on the Medicaid Drug Rebate Program, which factors in the average manufacturer price minus rebates. This ceiling price ensures that covered entities receive significant discounts compared to standard drug prices.

Who is considered a "covered entity"?

"Covered entities" are defined in statute and include:[8]

- Federal Grantees of the Health Resources & Services Administration (HRSA);
- Federal Qualified Health Centers;
- Qualifying hospitals;
- Children's Hospitals (in-patient facilities within patient predominantly age 18 or younger);[9]
- Critical Access Hospitals (rural health centers run by the Centers for Medicare and Medicaid Services);[10]
- Disproportionate Share Hospitals (hospitals that serve a significant proportion of low-income, uninsured, and Medicaid or Medicare patients);[11]
- Free Standing Cancer Hospitals (independent non-profit hospitals providing cancer treatment and care);[12]
- Rural Referral Centers (high-volume acute care rural hospitals that treat a large number of complicated cases);[13]
- Sole Community Hospitals (hospitals that serve as the only source of in-patient care for rural residents);[14]
- The Centers for Disease Control and Prevention (CDC);
- The Department of Health and Human Services Office of Population Affairs;
- The Indian Health Service; and
- Ryan White HIV/AIDS Programs Grantees.

What is a contract pharmacy?

A contract pharmacy is a retail or specialty pharmacy that dispenses 340B drugs on behalf of a 340B-covered entity, under a contractual arrangement. This arrangement enables patients to access discounted medications at pharmacy locations outside the covered entity's own facilities.[15]

What is a "child site"?

A child site in the 340B Program is an off-site, outpatient clinic or facility that is part of a 340B-covered entity, as demonstrated by its inclusion on the entity's Medicare cost report and registration in HRSA's 340B database. Once registered, it is eligible to purchase and dispense drugs at discounted 340B prices to eligible patients.[16]

What types of drugs are eligible for 340B discounts?

The Program applies to covered outpatient drugs, which are medications prescribed to patients who receive care without being admitted to a hospital. However, vaccines do not qualify for the discount, and orphan drugs (used to treat rare conditions) are excluded. Additionally, drugs acquired through group purchasing organizations by DSH hospitals, cancer centers, and children's hospitals are not eligible for 340B pricing.[17]

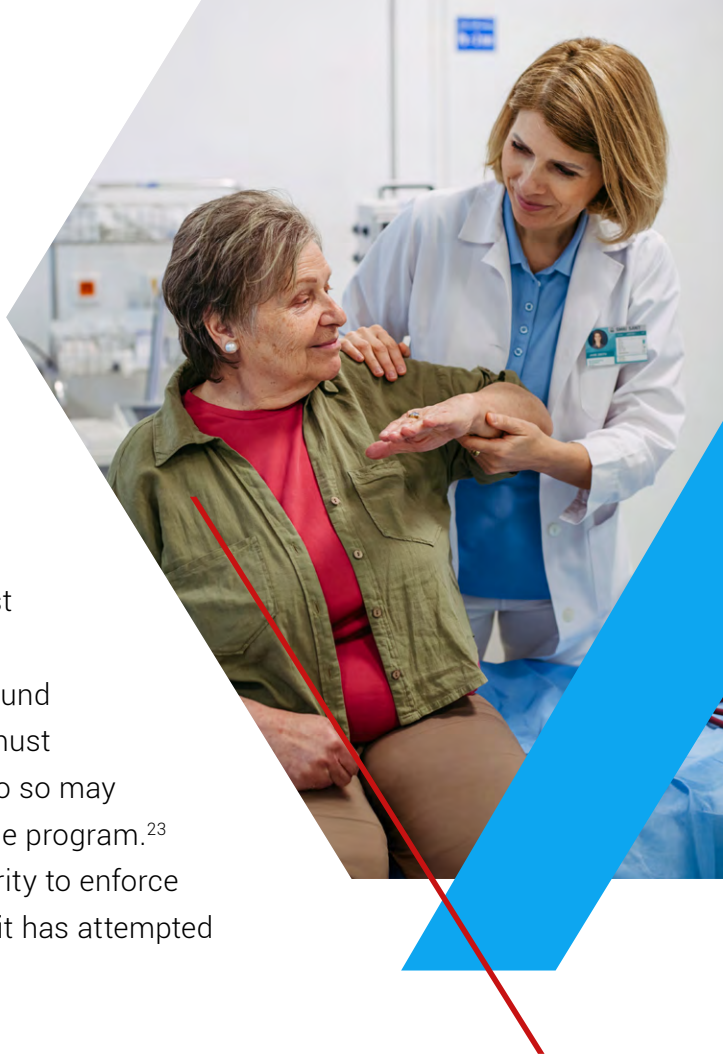
How are profits from the 340B program intended to be used?

Covered entities are expected to use 340B savings to maximize federal resources for vulnerable patients.[18] This may include expanding services, subsidizing operating costs, and improving access to medications.[19] However, the 340B program does not explicitly require covered entities to pass these savings directly to patients or to demonstrate their investments in outpatient programs.[20] Instead, the Program relies on covered entities to determine how best to use savings to benefit the populations they serve, without imposing specific reporting requirements on how the funds are used.[21]

Who is considered a 340B patient?

A 340B patient is someone who receives healthcare services from a 340B-covered entity, where the services are consistent with the entity's scope of grant or contract (for grantees) or are documented in the entity's records (for hospitals and other providers). The individual must have an established relationship with the covered entity, and the entity must maintain responsibility for the patient's care. Merely filling a prescription at a 340B contract pharmacy does not qualify someone as a 340B patient.[22]

What agency is responsible for ensuring the 340B Program benefits intended communities and individuals?



The Health Resources and Services Administration (HRSA), through its Office of Pharmacy Affairs, oversees the 340B Drug Pricing Program. HRSA's program efforts include verifying eligibility, conducting annual recertification, and performing audits of both covered entities and manufacturers. Covered entities must maintain accurate records, comply with rules against diversion and duplicate discounts, and may be removed from the Program or required to repay manufacturers if found noncompliant. Manufacturers are also subject to audits, must offer 340B drugs at or below the ceiling price. Failure to do so may lead to refunds to drug manufacturers or removal from the program.[23] However, courts have found that HRSA has limited authority to enforce the 340B Program requirements and oversight measures it has attempted to implement without additional legislation.

How has the evolution of the 340B program affected compliance?

The Program's lack of transparency and reporting requirements regarding the discounted prices paid by covered entities, the savings they generate, and how those savings are used, combined with policy changes that have allowed the Program to expand significantly, have raised questions over whether it still aligns with the program's original intent.[24]

How does the 340B Program impact health care consumers?

The 340B Program is an important safety-net program that allows covered entities to purchase prescription drugs at substantially discounted prices to ensure low-income patients have access to their necessary medications. Originally, the 340B Program was only intended to serve the patients directly associated with the covered entities.

However, as the program has grown, covered entities have created "pharmacy partners" to expand the reach of the 340B benefit.[25] Despite these profits, some hospitals are still providing less than the national average rates of charity care. Charity care is free or discounted health services provided to individuals who meet an organization's criteria for financial assistance and are unable to pay for their care.[26] As such, hospitals are generating increased revenue from the 340B Program while hundreds or even thousands of their patients are simultaneously incurring medical debt.

How has consolidation among PBMs and hospital systems affected overall health care costs?

Consolidation in the pharmacy supply chain has allowed a small number of PBMs to dominate, with a few major PBMs controlling 75% of all 340B contract pharmacy relationships.[27] In total, more than 94,000 contracts exist between 340B providers and pharmacies financially tied to the three largest PBMs.[28] Because PBMs control a large share of these contracted 340B pharmacies, much of the revenue from discounted prescriptions flows to them rather than being used to lower costs for patients.[29]

The profitability of 340B programs has also fueled consolidation in the broader health care market, as large hospital systems increasingly acquire smaller hospitals, clinics, and physician practices to capitalize on 340B-related revenues.[30] As a result, the program has contributed to higher costs for employers and workers rather than reducing the cost of care, particularly benefiting the largest hospital systems that capture most of the program's revenue.[31]

Road to Reform

The 340B Program was created to help safety-net providers deliver affordable medications to vulnerable patients. Over time, the program's operation has shifted in ways that can dilute its original purpose. Fortunately, both state and federal legislatures are considering a variety of reforms to return the 340B Program to greater transparency and accountability and ensure this program benefits the intended consumers. Fragmented efforts at addressing exploitation, whether by states or the private sector, risk producing inconsistent outcomes, highlighting the need for federal reform. Because the 340B Program is a federal initiative, any meaningful reform should be implemented at the federal level. Piecemeal changes risk creating a fragmented, inconsistent framework that undermines the program's uniformity and complicates compliance for both covered entities and pharmaceutical manufacturers. Ultimately, 340B reform can ensure benefits are delivered transparently and effectively, reinforcing the program's role as an objective tool to support equitable access to care.

The below chart explains the types of reforms currently being discussed on their impact on patients, providers, and hospitals.

REFORM	EXPLANATION OF PROBLEM	PROPOSED REFORM	IMPACT ON PATIENTS	IMPACT ON INDEPENDENT HEALTH CARE PROVIDERS	IMPACT ON HOSPITALS
Impose geographic limitations on contract pharmacies.[i]	HRSA guidance allows covered entities (CE) to utilize an unlimited number of contract pharmacies that are not required to be within a certain geographic location of the CE. This has led to the expansion of contract pharmacies into communities that do not serve low-income and underserved populations.[32] Combined with limited oversight, this has enabled CEs to profit from 340B contract pharmacy arrangements, often without benefiting the program's intended patients.[33]	Limit contract pharmacy arrangements by requiring pharmacy locations to be in geographical proximity of CEs serving the intended populations.[34]	Geographic restrictions, that don't recognize variations amongst rural and urban limitations, may restrict access for 340B patients.[35] However, this could also help ensure the program only serves its intended population instead of allowing CEs to profit by dispensing 340B drugs to non-eligible communities. This may also deter practices from steering beneficiaries to 340B hospitals for lower prescription drug costs for other medical services.[36]	Geographic restrictions would not directly impact health care providers.	340B hospitals would be limited to contracting with pharmacies within certain geographic limitations of the CE. This would limit the profitability of the 340B hospitals by restricting their leveraging of contract pharmacies in affluent areas.[37]
"Child site" limitations similar to Medicaid.	Limited oversight of the 340B program has incentivized hospitals to acquire off-site clinics in affluent areas with insured patients and register them under the 340B program, which are commonly referred to as "child sites." Child sites then become eligible for discounted drugs despite not providing discounts to the intended communities.[38]	Require that a child site be wholly-owned, clinically and financially integrated with the CE, provide care consistent with its policies, have fully integrated providers, medical staff, clinical services, medical records, and financial operations, and be publicly acknowledged as part of the CE's operations while meeting specific ownership requirements.[39]	Limiting child sites would not likely have a direct impact on patients. Limiting 340B child sites would help curb misuse of the program by narrowing participation to facilities that genuinely serve vulnerable and underserved populations, helping ensure that savings more directly benefit the intended individuals and communities.[40]	Addressing the use of "child sites" could require providers to be fully integrated with the CE, potentially increasing administrative burdens related to documentation, oversight, and compliance.[41]	Addressing the use of "child sites" would likely increase hospitals' administrative responsibilities to ensure compliance with program requirements[42] and would be barred from developing "child sites" that do not serve the intended 340B beneficiaries.[43]

[i] Some pharmaceutical manufacturers have imposed geographic limits on contract pharmacies eligible for 340B drug discounts to prevent program abuse. The 340B Report, Contract Pharmacy Restrictions Tracker, https://340breport.com/contract-pharmacy-restrictions-tracker/.

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Disclosure requirements for how savings are passed down to consumers.	The 340B program does not require CEs to pass drug discount savings directly to low-income or uninsured patients. Instead, the program only carries an implied expectation that savings will be reinvested to improve access to care[44] for "covered" patients, which are those receiving regular medical care at the hospital or its outpatient affiliates.	Require CEs to report detailed information regarding their program savings, policies, patient, and prescription information.[45]	Increasing disclosure requirements would not likely have a direct impact on patients. However, disclosure requirements would increase accountability to help ensure the 340B program savings serves low-income or uninsured patients which would impact consumers later on.[46]	Increased disclosure would not likely directly impact health care providers.[47]	Increased disclosures would likely increase hospitals' administrative responsibilities and require them to demonstrate that 340B savings are benefiting the intended individuals.[48]
Patient eligibility requirements.	Congress's failure to clearly define a "patient" has created ongoing uncertainty and misuse of the 340B Program.[49]	To promote greater clarity, accountability, and program integrity, legislators are consider amending the 340B statute to include a clear and uniform definition of "patient."	A new definition of "patient" would not likely impact patients, unless they were improper beneficiaries of the 340B Program as a new definition would likely disqualify them or remove them from a 340B Program.[50]	A new definition of "patient" would not likely impact providers, but could help address practices that steer patients away from community practices to larger health systems and hospitals.	A new definition of "patient" would likely impact hospitals as they would be required to ensure all 340B individuals satisfied the definition of "patient."
Strengthened program compliance oversight.	A GAO report highlighted significant oversight gaps in the 340B program, identifying over 1,500 instances of non-compliance with regulations between 2012 and 2019, underscoring the need for stronger enforcement to ensure program integrity.[51]	Implement clearer compliance standards and expand program compliance oversight, including stronger monitoring and auditing processes, and more frequent program reviews.[52]	Increased compliance and oversight will not likely impact patients.[53]	Increased compliance and oversight would likely impose additional administrative responsibilities on health care providers to ensure accurate recordkeeping and demonstrate program compliance.[54]	Increased compliance and oversight would likely impose additional administrative responsibilities on hospitals to ensure compliance with the law. This may also reduce hospitals' profits from the program by limiting opportunities for misuse and noncompliance.[55]

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Enforcement authority for HRSA.	HRSA oversees the administration of the 340B program, but its authority for enforcement and oversight is limited. When audits find program violations, they rarely result in penalties.	Empower HRSA to have greater enforcement authority and impose penalties for non-compliance with 340B program requirements.[56]	Increased authority to HRSA will not likely impact patients.[57]	Increased authority to HRSA will not likely impact health care providers.[58]	Increased authority to HRSA will not likely impact hospitals.[59]
Transparency requirements around medical debt and charity care.	In 2021, 36% of 340B Hospitals allocated less than 1% of their operating costs to charity care despite increased profits due to 340B revenue.[60]	Require 340B hospitals to report detailed data on the amount of free or discounted charity care provided to uninsured, low-income, and vulnerable patients, along with transparency in their debt collection practices.[61]	Increased transparency surrounding medical debt could improve debt collection practices that can result in financial challenges for patients.[62]	Increased transparency requirements around medical debt and charity care would not likely impact health care providers.[63]	Increased transparency requirements around medical debt and charity care would likely result in additional administrative responsibilities for hospitals to comply with reporting requirements.[64]
Duplicate discount prevention.[ii]	The 340B Program and the Medicaid Drug Rebate Program both require drug manufacturers to offer discounts. However, federal law prohibits "duplicate discounts," which occur when the same drug receives both a 340B discount and a Medicaid rebate discount. Due to limitations in HHS oversight, there is limited tracking and monitoring of this practice.[65]	Establish a national clearinghouse to collect claims-level rebate data, identify potential duplicate discounts, and require CEs to repay manufacturers when violations are found.[66]	Addressing duplicate discounts would not likely impact patients.	Addressing duplicate discounts would not likely impact health care providers.	Addressing duplicate discounts would increase the administrative responsibilities of hospitals. A national clearinghouse would increase hospitals' administrative responsibilities by requiring detailed claims reporting and could expose them to financial penalties for duplicate discounts.[67] However, it would also promote greater accountability and may encourage more targeted, compliant use of 340B funds.

[ii] The HRSA has launched a voluntary 340B Rebate Model Pilot Program to test a new approach where covered entities purchase drugs at wholesale acquisition cost (WAC) and later receive rebates from manufacturers. HRSA, 340B Rebate Model Pilot Program, https://www.hrsa.gov/opa/340b-model-pilot-program.

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