

GCOA Alliance for Health Innovation Policy Brief: The 340B Drug Pricing Program

340B Reform: Recommendations to Support Healthy Aging & Health Innovation

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TABLE OF CONTENTS

Introduction & Policy Background	2
340B Program: The Impacts on Healthy Aging	4
Impacts on Innovation	9
The Need for Federal 340B Reform	10

Introduction & Policy Background

The federal 340B Drug Pricing Program was established by Congress in 1992 to help low-income and uninsured patients access their treatments. The 340B program enables eligible healthcare providers (known as "covered entities") – such as hospitals and local health clinics – that serve a significant proportion of those more vulnerable patient populations to purchase outpatient drugs from biopharmaceutical manufacturers at a significant discount. The program was designed with the intent that 340B covered entities would use savings from drug discounts to provide patients in need with more affordable and accessible care.

However, there is inconsistency in how hospitals, health clinics, and other entities that participate in 340B demonstrate how they use savings from the purchase of discounted drugs to provide care to the patients the program was intended to serve. At the same time, for-profit pharmacy benefit managers (PBMs) - through their ownership of and affiliation with pharmacies that contract with 340B entities (known as "contract pharmacies") - are silently siphoning away critical dollars and increasing the burden on American patients, families, and employers, instead of passing savings to the low-income populations the program was designed to support.1 This lack of transparency and accountability in the 340B program has fueled abuses, allowing 340B covered entities, national pharmacy chains, and forprofit middlemen to exploit the program for financial gain.

Despite the vast size of the 340B program, there is a lack of data, or requirements to report such data, on how covered entities spend savings generated through the program or the abusive business tactics contract pharmacies and PBMs implement to maximize revenue from the program. This lack of transparency hampers efforts to evaluate whether the program is advancing access to care for in-need communities or merely financially benefiting covered entities and other for-profit actors.

340B is currently the second-largest prescription drug program in the country, expected to surpass Medicare Part D, Medicaid Part B, and Medicaid in size by 2028.^{2, 3} In 2023, discounted drug purchases under 340B totaled over \$66.2 billion.⁴

Contract pharmacies profit significantly from the 340B program, with national pharmacies earning \$7 billion annually – 28% of total 340B revenue. CVS recently credited the 340B program as one of three major drives for their above-expected revenue.

"Today, just as when 340B began in 1992, far too many Americans are having a hard time paying for medicines and need help. Yet 340B has not fulfilled its promise to help low-income and uninsured patients access outpatient medicines. It's time for lawmakers to put an end to this corruption of legislative intent and enact meaningful reforms that ensure the program offers a genuine lifeline for patients who need it most."

Peter Pitts, Center for Medicine in the Public Interest (CMPI)

Key Challenges: 340B Program Transparency & Abuse

1. Lack of Reporting Requirements:

The 340B program does not require covered entities to disclose how they use revenue generated from drug discounts or how these funds benefit patients. Similarly, overly broad criteria have led to a surge in the number of covered entities participating in the 340B program, raising questions about whether resources are being directed toward truly underserved populations. This opacity makes it difficult to assess whether the program is fulfilling its mission of improving care for populations in need. 10

The number of contract pharmacies is rapidly increasing in high-income areas, while the proportion of 340B contract pharmacies that support socioeconomically disadvantaged areas is declining.¹¹

3. Lack of Charity Care:

Evidence suggests that some participating hospitals may not reinvest 340B savings into safety-net care as intended. Data shows that, compared to revenue, 340B hospitals provide <u>less charity care</u> than the average hospital.¹⁴

A 2024 <u>study</u> showed that approximately 85% of disproportional share hospitals (DSHs), which frequently receive 340B discounts, earned an estimated \$44.1 billion in 340B profit in 2022 while spending only \$18.5 billion on charity care.¹⁵

2. Expansion in Affluent Neighborhoods:

Due to a lack of oversight within the 340B program, there is a perverse incentive to maximize revenue by gaining access to a larger pool of well-insured patients.

Hospital-covered entities often acquire practices and health clinics that do not serve low-income patients to increase their profits. Yet, consolidation frequently results in <u>higher prices for patients</u> and a loss of quality and localized care. 12, 13

4. Increased Burden on American Employers, Health Plans, and Families:

The exploitation of the 340B program also drives up costs and increases burdens on American employers, health plans, and families. When a prescription has both a 340B discount and a commercial rebate applied, manufacturers can cancel the rebates to prevent "stacked discounts." In these cases, the cost burden is shifted to the employer – the covered entity retains the 340B revenue, but the employer loses the rebate that would have lowered premiums, ultimately impacting employees' take-home pay and access to care.

These challenges, created by misuse and abuse of the 340B program and enabled by loopholes and the lack of accountability outlined in the original statute, have a direct impact on patient communities and the broader healthcare ecosystem. In recent years, a growing number of state legislatures have introduced legislation related to the federal 340B program, creating a confusing patchwork of policies across the country that makes an already complex system even more challenging to navigate and exacerbates the opportunity for for-profit middlemen to exploit loopholes in 340B for their financial benefit.

Only through comprehensive federal reforms can the necessary transparency and accountability measures be instituted to 340B to ensure it is carrying out its original intent and mitigate negative impacts on the supply chain.

Rather than supporting the U.S. healthcare system's safety net, for-profit entities are siphoning funds out of the 340B program for their own financial benefit. One analysis showed that national pharmacies are generating \$7 billion in annual profits through the 340B program. This ultimately increases government spending and the burden on the healthcare infrastructure as patients seek more expensive care at later stages.

A report from the North Carolina Treasurer's Office concluded that "340B hospitals have used the State Health Plan to extract significant profits from taxpayers and state employees." 17

340B Program: The Impacts on **Healthy Aging**

According to the most recent census data from 2020, 16.8% of the U.S. population is age 65 and older. 19 From 1920 to 2020, this age group grew five times faster than the general population, thanks in part to continued innovation and access to medicines that help extend lifespans and improve quality of life. Chronic conditions, including diabetes, heart disease, HIV, and cancer, disproportionately impact older adults. Rates of chronic conditions in older Americans are set to double by 2050.20 Many older adults rely on prescription medications to manage chronic conditions.

The 340B program was designed to help access their medications, patients particularly for those who are uninsured or underinsured.

Because Medicare provides a public coverage option for individuals in the U.S. aged 65 and older, less than 1% of Americans over 65 are uninsured.²³ However, through Medicare Advantage and private health plans, insured patients still face barriers to accessing the treatments they need due to complex administrative burdens and high co-pays.

Abuse of the 340B program has an impact on opportunities for healthy aging and the ability of older adults to access their medications. Treatments for conditions disproportionately affect older populations account for a significant percentage of total sales within the 340B program. In turn, abuse of the 340B program by covered entities and middlemen, and the lack of transparency in the charity care provided to patients disproportionately impact aging adults.

95% of Americans age 60 and older are living with at least one chronic condition.²¹

of Americans age 60 and older are living with two or more chronic conditions. ²²

of people with Medicare coverage reported it was difficult to afford their healthcare. ²⁴

of insured American adults say they have skipped or postponed necessary medical care or medications in the 12 months because of costs. ²⁵

Therapeutic Area	Percentage of Overall 340B Sales	Percentage of Patients Age 55 & Over
Cancer (Targeted Oncology Treatments)	~35% ²⁶	80.2% ²⁷
Hepatitis C & HIV (Anti- Viral Treatments) ~36% ²⁸	~36%20	HIV: 41% ²⁹
		HCV: 50+% ³⁰

In 2023, the <u>top ten drugs</u> in terms of 340B purchases, which included five treatments for cancer and two for HIV, accounted for approximately one-third of the total spending in the 340B program.³¹

Advancing age is the most important risk factor for cancer overall and for many individual cancer types. With cancer treatments making up а significant proportion of the total sales of drugs within 340B, the program has a considerable influence over the cancer care delivery system and the health of aging adults in the U.S. As 340B entities are incentivized to purchase higher-cost drugs through 340B, patients with cancer and other conditions are forced to shoulder the burden of greater out-of-pocket costs.32

An analysis of claims data from 2022 indicates that 10 percent of the 340B oncology drug margin, which equates to approximately \$800 million, is funded by patients.³³

As the 340B program expands, many covered entities and the national, for-profit pharmacy chains they contract with are reliant on 340B funds as a key revenue stream.

340B health clinics mark up their drugs for patients and payers by over 3.7 times the 340B discounted price, and hospitals mark up the price of medicines 6.6 times higher than independent clinics. 34, 35

The average <u>profit margin</u> for contract pharmacies on commonly dispensed 340B drugs is 72%, compared to 22% for non-340B drugs.³⁶

Walgreens charges 340B covered entities an administrative fee of <u>anywhere between 8%</u> and 20% of the contracted reimbursement rate for private insurer patients each time its contract pharmacies fill a 340B prescription.³⁷

Due to the lack of data visibility in the 340B program, PBMs and middlemen are increasing profits by capturing duplicate discounts from serving more commercially well-insured patients. IQVIA <u>estimated</u> that \$20-25 billion in duplicate discounts were issued through the 340B program in 2021.³⁸

Health clinics account for over \$17 billion of annual gross 340B program sales from the program in a single year and generate up to 70% of their 340B drug margin from public payer reimbursements (Medicaid and Medicare) – purchasing discounted drugs and reselling them at markup through for-profit national pharmacy chains increases costs for taxpayers.^{39, 40}

In many cases, covered entities purchase drugs at 340B discounted rates and charge vulnerable patients the original, full cost of the drug, pocketing the difference as profit. As the number of relationships between 340B covered entities and contract pharmacies has rapidly increased, the proportion of 340B contract pharmacies in socioeconomically disadvantaged areas has declined.41 This signals that, in an increasing number of cases, for-profit pharmacy chains and their intermediaries are generating profits as their affiliated contract pharmacies target areas where they can extract the most revenue from the 340B program. All the while, patients, who are frequently unaware that their drug was purchased at a 340B discount, shoulder the full cost.

This profiteering system creates barriers to accessible care for vulnerable patients. Insured patients, including older adults who frequently rely on multiple prescription medications to manage chronic conditions, are paying the full cost of a drug. At the same time, 340B entities receive deep discounts, sometimes paying as little as a single penny.⁴²

"340B dollars are intended to support patient access to care, but exploitative behavior — such as foisting the financial burden of medical care onto patients and predatory debt collection practices — will only worsen as 340B grows without sufficient guardrails to protect patients."

Jen Laws, Community Access National Network (CANN)

Impacts on Innovation

As covered entities often fail to utilize 340B drug discounts to benefit patients, these funds also do not flow back into the life sciences ecosystem that brings innovative treatments to patients and enables healthier aging. Many diseases that once burdened populations aging have evolved manageable chronic conditions due safer. and modern. more effective treatments, allowing many patients to live longer, healthier lives.

The absence of transparency into how these dollars are used to help patients allows the funds to be diverted into profits for bad actors rather than being invested into the development of innovative healthcare solutions that will bring better health outcomes and longer, healthier lives for patients. For instance, funds generated through the 340B program could be used to develop new models of care or expand access to cutting-edge treatments; however, they are instead untracked and unregulated.

Rather than serving patients directly or through the advancement of vital research and discovery efforts, the savings derived through the purchase of 340B discounted medicines are instead serving to pad the bottom lines of hospitals, health clinics, other covered entities within the program, and forprofit pharmacy chains and middlemen in the healthcare system.

The Need for Federal 340B Reform

Loopholes and structural flaws in the 340B Drug Pricing Program have led to revenue generation, rather than the care of vulnerable patients, becoming the primary concern for many covered entities. The design of the 340B program encourages a focus on maximizing profit, whereby covered entities are incentivized to leverage the program to mark up and resell as many discounted drugs as possible to insured patients, thereby retaining the profits.

While we recognize that the 340B program can play a crucial role in increasing access to innovative treatments for patients, particularly those in rural or underserved areas, the evidence suggests that the program has deviated from its intended purpose. Ongoing challenges related to transparency and policy shifts could impact effectiveness in supporting population, leading unintended to consequences that affect access to critical, life-saving medication and services, and ultimately reduce the promise of healthy aging for all Americans.

Given how hospitals, for-profit pharmacy chains, and health system middlemen are exploiting loopholes in the 340B program, federal reforms are necessary to ensure that the savings generated through the purchase of 340B-discounted medicines are used to increase access for the most vulnerable patient communities.

"Supporters of the 340B drug discount program emphasize the vital work hospitals engage in to treat low-income people. If this program were designed to achieve that aim, then it might not be so bad. Sensible reforms could be implemented. These include establishing a definition of a patient to receive the discounted drug that reflects a financial need, limiting the ability of entities to acquire practices in higher income areas that the program is not designed to serve, implementing a system that monitors for duplicate discounts, or requiring the money earned from the 340B program is used to deliver patient care to low-income people."

Kirsten Axelsen, American Enterprise Institute (AEI)

While state legislatures have been active on issues related to the 340B program within their borders, the 340B program is a federal program. It therefore requires comprehensive federal reform to ensure that it fulfills its originally intended purpose of serving vulnerable patient populations, rather than serving as a profit center for hospitals and pharmacies.

To address these issues, several federal policy reforms could be considered:

- 1. Mandatory Reporting: Require 340B claims transparency and covered entities to disclose detailed information on how 340B savings are used, including specific investments in <u>patient</u> care and community health programs.⁴³
- 2. Stricter Eligibility Criteria: Narrow <u>eligibility</u> requirements to ensure that only truly safety-net providers benefit from the 340B program.⁴⁴
- 3. Enhanced Oversight: Implement <u>regular audits</u> and compliance checks by federal agencies, such as the Health Resources and Services Administration (HRSA) and the Centers for Medicare & Medicaid Services (CMS), to prevent misuse of funds. 45

The implementation of these federal reforms would represent meaningful steps toward returning the 340B program to its original intent.

By increasing transparency and accountability through comprehensive federal reform, the 340B program could better align with its original mission of supporting vulnerable populations while fostering equitable access to care and innovation.

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