



Research

PRIMER: The 340B Drug Pricing Program – Challenges and Solutions

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Executive Summary

- The 340B Drug Pricing Program has grown dramatically since its inception in 1992, and especially in the years following the passage of the Affordable Care Act.
- While the program has increased hospital profits, it has arguably failed to accomplish its supposed goal—to increase care at reduced costs for patients and the federal government.
- Reforming 340B will require a clear statutory purpose for the program, increased transparency and accountability measures, and more explicit guidance around how 340B savings may be used by covered entities.

Introduction

Congress established the 340B Drug Pricing Program in 1992 to provide covered entities (CEs) with discounted drugs to correct for a side effect of the Medicaid Best Price rule that ended manufacturers' charitable donations of medicine to hospitals. (For more information on the history and basics of the 340B Program, read the recent American Action Forum primer on the subject [here](#).) While the 340B Program is rooted in good intentions, it suffers from a lack of much-needed purpose, transparency, and accountability. The lack of statutory purpose has ensured that the program's intent, execution, and desired outcomes are frequently debated with no resolution. The formula used to calculate 340B eligibility for hospitals does not accurately represent the program's generally agreed-upon target patient population of the indigent and uninsured. The program's rapid expansion under the Affordable Care Act (ACA) led not only to significantly more participants and less transparency, but increased conflicts with drug manufacturers that had to provide discounts to a far greater number of entities that were not consistently using those discounts in line with the program's vague mission. What's more, the amount of charitable care participating hospitals provide is less than that of non-participating hospitals, even though a driving reason for establishing the 340B Program was to enable charitable care. Attempts by the Health Resources and Services Administration (HRSA) to enforce accountability in the program have been ineffective at tracking and preventing violations such as duplicate discounts and diversion. 340B's core problems have fed into each other and worsened with its rapid expansion; the outcome is that patients are often not benefiting from the mandatory discounts covered entities receive through the program. This paper explores how the 340B Program's three key challenges issues interweave with each other, considers the consequences, and offers potential solutions.

Problems with the 340B Program

Lack of Purpose

The 1992 House report that accompanied the passage of the initial legislation creating the 340B Program stated that its purpose is “to enable entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”^[1] This legislative report language is not only vague, but (as is any legislative report language) non-binding; the statutory language doesn’t provide a great deal of clarity, as it does not specify what the program is meant to accomplish, but merely *how it works*. There is some broad consensus about what 340B was meant to accomplish: The program was created in response to the end of charitable medicine donations caused by the Medicaid Best Price Rule, and the savings created by 340B are intended to help hospitals help patients. Yet how, exactly, the program’s savings are meant to help patients, and which patients should receive that help, are ongoing points of debate between CEs and pharmaceutical manufacturers.

The question of purpose persists when it comes to eligibility for the program. For CEs to be eligible, they must have some sort of contract with a state or local government, but no criteria exist for any specific provisions those contracts must contain.^[2] A hospital’s Disproportionate Share Hospital (DSH) percentage (the percentage of Medicaid and low-income Medicare patients) is used to determine program eligibility but does not establish how much uncompensated care a hospital is providing. Additionally, “eligible patients” are currently defined as individuals with an established relationship to the CE, which in practice can mean any patient, insured or uninsured, who receives care even once.

Transparency Issues

The 340B Program’s transparency issues revolve around a few factors: Determining patient eligibility to receive 340B drugs, ensuring that only eligible patients receive 340B drugs, and determining which discounts are applied to which drugs.

First, let’s look at the problem of ineligible patients receiving 340B drugs. This is called “diversion,” and results in discounts being given beyond the legal scope of the program. Because the definition of an eligible patient for 340B is so broad, CEs frequently use different criteria to determine which patients are considered eligible, meaning the same patient may be included or excluded from eligibility purely based on an individual CE’s interpretation of the definition. Additionally, growth in the use of contract pharmacies has created an added layer between the patient and the CE, increasing the difficulty of determining whether a patient is eligible (see Textbox 1 for details on this complexity). The Office of the Inspector General (OIG) at the Department of Health and Human Services (HHS) has found a variety of instances over the years in which CEs have either lacked the tools or were using ineffective tools to screen for diversion problems.^{[3],[4]}

Another transparency issue is that of “duplicate discounts.” A duplicate discount occurs when a manufacturer provides a CE with a 340B drug discount as well as a Medicaid Drug Rebate Program (MDRP) discount to a state Medicaid program for the same drug and the same patient. This practice is statutorily banned and 340B rules require CEs to carve in or carve out Medicaid patients for 340B discounts. Nevertheless, there have been numerous instances in which the OIG has found that CEs (and even state Medicaid programs) often have no way to discern whether duplicate discounts have been created.[5]:[6] Simply put, CEs and contract pharmacies are not abiding by recommended HRSA guidance on how to best track which drugs are eligible for the 340B discount and which are eligible for the MDRP discount.

Money-Product Flow in 340B

To illustrate the complexity of the 340B system, below is a simplified version of the money-product flow in a single interaction of an insured patient eligible for the 340B Program getting their drugs from a contract pharmacy.[7]

1. A patient has a prescription filled at the pharmacy and pays the co-pay, while the patient’s insurer (private or public) pays the rest. Both the co-pay and the insurer’s portion are paid to the pharmacy. The amount paid is not based on the 340B price, but previously negotiated prices with the insurer.
2. The pharmacy then checks to see if that patient was prescribed the drug at a CE and if that CE considers the patient eligible for 340B drugs. How the pharmacy determines an eligible 340B patient depends heavily on the procedures the individual pharmacy and CE have established, as there are no federally standardized procedures, though third-party administrators (TPAs) are often used. Assuming 340B eligibility is confirmed, the pharmacy then asks that CE to refill the prescribed drug on behalf of the pharmacy. In the meantime, the pharmacy reimburses the CE for the drug refill with the money it was paid by the insurer and the patient, minus some fees.
3. The CE puts in a refill order at a wholesaler, which will ship the refill to the pharmacy. The CE will then pay the wholesaler, as well, but at the 340B price of the drug.
4. The wholesaler then submits what is known as a “charge back” to the manufacturer for the difference of the 340B price and its wholesale acquisition cost (WAC) – essentially, charging the manufacturer to pay the remainder of the WAC not covered by CE’s 340B payment.

It should be made clear that neither the patient nor the insurer is guaranteed to receive any direct benefit from the 340B Program. There is no requirement that CEs pass along discounts to eligible patients. Additionally, the pharmacy records kept by a TPA are not always accurate. Communication between the pharmacy, TPA, and CE may also break down in trying to determine a patient’s eligibility.

Accountability

The 340B statute does require CEs and manufacturers to keep auditable records, and HRSA does conduct spot audits from time to time, under the premise that the threat of an audit will keep most actors in line.[8] Audits are conducted at the expense of either HRSA or a manufacturer, depending on which initiates the audit. Naturally, the expense involved is a deterrent, though it also prevents excessive audits by manufacturers. CEs, and manufacturers after an audit, may initiate a dispute resolution process to have HRSA resolve claims of malfeasance by the other party. Whether through audit or dispute resolutions, parties found to be in violation of 340B guidance must either pay the party that brought forth the dispute what is owed them (e.g., a manufacturer found in violation of ceiling-price rules would have to pay back a CE the amount it was overcharged), or in more extreme cases, be removed from the 340B Program.[9] But with tens of thousands of CEs and hundreds of manufacturers, HRSA does not have the manpower to audit even a small fraction of 340B participants.

In 2020, there were 12,700 CEs participating in 340B. HRSA conducted 200 audits that same year and found 15 instances of diversion and 43 instances of duplicate discounts.[10] It is not known if these audits, which covered only 1.57 percent of all CEs, are representative of all CEs. A 2020 Government Accountability Office (GAO) report found that HRSA does not require covered entities to address duplicate discounts in Medicaid managed care or to work with manufacturers to repay those discounts. Additionally, the 2020 GAO report found that HRSA audits do not review state policies and so cannot see if the 340B Program is following state requirements to avoid creating duplicate discounts. Similarly, the 2020 report found that the Centers for Medicare and

Medicaid Services does not have the necessary information to ensure that 340B drugs are excluded from Medicaid rebates.[11]

The Cost of 340B

All of these issues are adding costs to a program that is exploding in growth. In 2005, there were 583 340B CEs. In 2010, that number grew to 1,365, and in 2014, there were 2,140 CEs.[12] By 2020, there were around 12,700 participating CEs.[13] The numbers for contract pharmacies are similar: From 2010 to 2014, the number of contract pharmacies grew by 154 percent.[14] In 2010, there were around 1,300 contract pharmacies; that number has grown dramatically to 29,971 in 2021.[15] Much of this growth has been due to the passage of the ACA. This growth has spurred massive cost increases, as well. In 2014, the value of purchases by CEs at 340B prices was \$9 billion; in 2021, the value was \$38 billion.[16]

These costs are not solely borne by pharmaceutical manufacturers. Neither Medicare Part B nor Part D benefit from 340B discounts when they pay for 340B drugs, and nor do any private insurers. Both Parts B and D pay average sales price (ASP) plus 6 percent for 340B drugs, and private insurers pay their standard pre-negotiated rates. This is significant not only in payer costs, but also in beneficiaries' co-pays, which are based on the full price of the drug (or for Medicare beneficiaries, 20 percent of the total cost to Medicare). There are concerns that 340B discounts, which can range on the low end from 22.5–100 percent of a drug's cost, have become so numerous and large that they are driving up the costs of 340B drugs in private markets as well as non-340B drugs to account for decrease in profits.

On the federal side, the Medicare Payment Advisory Commission (MedPAC) reported that in 2015 340B hospitals received on average a minimum discount of 22.5 percent of the ASP.[17] 340B discounts average 42 percent of the AASP, while one-third of drugs under Medicare have a 340B discount over 80 percent of ASP. [18] The HHS Office of the Inspector General found that in 2013 payments made by Medicare Part B and the coinsurance paid by beneficiaries for 340B drugs were 58 percent higher than the ceiling price that may have been charged to the hospitals to obtain the drugs; this difference between the cost to the hospital and the reimbursement to the hospitals allowed hospitals to retain approximately \$1.3 billion that year from 340B discounts, alone.[19]

The costs may even extend beyond just drug expenditures: The GAO has found 340B participation to be associated with higher Medicare expenditures. In 2012, average spending per Medicare beneficiary at 340B hospitals was more than double the expenditures at non-340B hospitals, and this difference was not explained by patients' health status.[20] It should be noted that at least one recent study has called that GAO conclusion into question, showing that when hospital characteristics and patient mix were accounted for, there was no significant difference in Medicare spending between 340B and non-340B hospitals.[21] A preliminary analysis conducted by AAF, using 2021 Medicaid data from the research firm 46brooklyn, shows that nationally, state Medicaid programs paid an average of 201.8 percent above 340B acquisition costs.[22] This number was calculated by taking all 50 states' average acquisition cost for all drugs and finding the difference between the average 340B price for all drugs in those 50 states, which 46brooklyn calculated using the 340B prices found in Texas Medicaid data.

In 2019, 340B hospital operating profits stood at 2.1 percent, compared to 1.7 percent for non-340B hospitals, with an estimated \$17.7 billion in profits from 340B.[23] For Federally Qualified Health Centers, total margins averaged 5 percent and in some cases have reached as high as 37 percent, in large part due to the 340B Program. [24] It is not disputed that CEs are making a profit from 340B drugs—the program allows for this. But there are concerns about how these profits are used, as 340B hospitals provide less charity care than the average of all

hospitals. The average percentage of charity care compared to patient revenues for all hospitals in 2017 was 2.03 percent. The average percentage of charity care for 340B hospitals was 1.66 percent, meaning non-340B hospitals provided much more charity care than 340B hospitals, despite receiving no discounts from the 340B Program.^[25] Additionally, uninsured patients can be entirely on the hook for the full price of the drug, as the CE can choose whether to pass on the 340B discount to the patient. HRSA does not have statutory authority to track how CEs spend their 340B savings, so official estimates are not available, but non-governmental studies have shown that roughly 56 percent of funds do not go to the patient.^[26]

Potential Solutions

The 340B Program is politically fraught, with billions at stake for CEs, manufacturers, PBMs, and pharmacies. Change to the status quo should not be undertaken lightly. Several attempts to clarify patient definitions, CE eligibility, payment rates, usage of discounts, and other issues have all ended up in the courts and most have been rescinded. In many of these cases, the argument against the changes is that they were done through rulemaking not permitted by statute. Any serious reform to 340B will require congressional action. Below are some of the major reform ideas in the public discussion.^[27]

Purpose

The 340B Program currently lacks statutory purpose. A general understanding that 340B is supposed to help patients is not enough and has led to abuse of the program. We propose that a statutory purpose for 340B be constructed along the following guidelines:

1. Defined intent: What is the goal of the program?
2. Defined patient population: Whom is the program meant to serve?
3. Defined use: How are the savings CEs obtain through the program to be used?

An example following these guidelines might look like this: “The intent of the 340B Program is to provide discounts on pharmaceutical drugs to hospitals that serve indigent populations, and the savings from these discounts shall be used to provide services to indigent patients.”

These guidelines would help address the largest concerns surrounding the 340B Program and illuminate the reality of how the program is used by CEs today without disrupting its function.

Transparency

The 340B Program needs significant safeguards to ensure transparency. While not every entity is abusing the program and taking advantage of its patients, the preponderance of evidence shows a clear need for significant reform and stronger oversight to ensure program integrity. Currently, only federally funded health centers and clinics are required to publicly disclose how they use the savings received from 340B discounts. Hospitals should have similar obligations. Alternatively, 340B hospitals could be required to pass the savings directly to the qualifying patients. Most hospitals **claim** the savings they receive are used toward patient benefits, such as increasing the number of services available to patients, and this may be true. But taxpayers deserve to know that the tax benefit received by these not-for-profit hospitals is justified. Once these rules are updated, penalties for non-compliance must also be enhanced. The current response—temporary ineligibility—does little to deter bad actors.^[28]

Eligibility

340B Program eligibility should also be reformed. The metric for determining an entity's eligibility for the program should be adjusted to ensure participating hospitals are primarily serving the targeted beneficiaries. The current metric for eligibility is based on the share of low-income Medicare and Medicaid inpatients at a hospital, but the program provides a discount for drugs provided to outpatients and is intended to be used for uninsured individuals, which, of course, does not include Medicare and Medicaid beneficiaries. Moreover, the calculation does not include the percentages of patients at hospitals' child sites, which further skews the eligibility metric. These child sites are more likely to be in wealthy areas with lower rates of uninsurance, yet they receive the 340B discount without affecting the CE's eligibility.[29] This mismatch results in many entities inappropriately benefiting while other entities with much greater amounts of charity care do not. Along these lines, a clearer and stricter definition of an eligible patient is necessary. The current definition is too broad and allows for many more drugs to be obtained at a discount than originally intended.[30]

Authority

Finally, HRSA needs more authority to promulgate regulations that will bring the program in line with its original objective as a safety-net program and additional resources to provide sufficient oversight. HRSA does not have the authority to require hospitals to report the amount of funds they generate from the program or how those funds are spent. HRSA also does not have the authority to share ceiling prices with state Medicaid programs so that the states may ensure they are not paying for duplicate discounts. Use of a 340B claim identifier could likely help in this regard. HRSA has only 22 full-time employees dedicated to oversight of the 340B Program, primarily due to a lack of funds and direct hiring authority, making its provision of adequate oversight impossible.[31]

Conclusion

Originally created to counter the unintended consequences of the Medicaid Best Price rule, the 340B Drug Pricing Program is fraught with myriad unintended consequences. The program lacks purpose, transparency, and accountability, and these factors—combined with its increased growth—have led to more costs for the taxpayer, beneficiaries, insurers, and pharmaceutical manufacturers. Additionally, the program is not particularly effective in accomplishing its main, albeit vague, goal of stretching “scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services,” with charity care lower in 340B CEs than in non-340B hospitals. As it stands, congressional action is needed, both to clarify the program's purpose as well as empower HRSA to make the changes necessary to turn 340B into an effective program.

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- [10] <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-20-results>
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[20] Ibid.

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[31] Ibid.