The 340B Program: Once a Safety Net Program, Now a Program that Fails Vulnerable Patients

The 340B drug pricing program was designed to help improve access to medicines for vulnerable, low-income patients through manufacturer discounts to specific qualifying hospitals and federally funded clinics. Unfortunately, the program has strayed far from its purpose, with more and more health care entities using these deep discounts for themselves. A recent *New York Times* investigation illustrates one of the ways in which the program is often abused to serve as a profit growth engine for wealthy hospital systems. The investigation demonstrated how a large hospital system is underinvesting in its 340B hospital that serves lower-income patients and patients of color.[i] Meanwhile, the hospital system is using those patients so that it can access 340B discounts and invest in expanding outpatient facilities in wealthier areas. Unfortunately, this is just one of many examples of health care entities manipulating the program to benefit their bottom line. At this point, it seems patients are the only ones not benefiting from the billions of dollars in discounts manufacturers provide each year through the 340B program.

Many patients are not benefiting from the program today.

Today, nearly 60% of all hospitals in the United States participate in the 340B program,[ii] but there is no evidence that this expansion of the program has translated into improved access to medicines for patients. In fact, 65% of 340B disproportionate share hospitals (DSH) have charity care rates below the 2.9% national average for all hospitals, meaning these supposed safety-net hospitals are spending less than 2.9% of their operating expenses on free or discounted care for vulnerable patients.[iii] There is a big disconnect when hospitals participating in the 340B program are providing below-average levels of charity care to the communities they are intended to serve.

Part of the problem is there are no requirements for how hospitals participating in the program use the profit they make from 340B. Today, hospitals buy 340B outpatient medicines at a significant discount - averaging 59% - and then they mark up the price and charge patients and many payers the higher price.[iv] 340B hospitals then capture the difference between the discounted 340B price they pay and the higher reimbursement they receive. One study found that commercial insurance reimburses 340B hospitals on average three times what the hospitals paid for the physician-administered medicines.[v] And both the Government Accountability Office (GAO) and Department of Health and Human Services Office of Inspector General (OIG) have found that 340B hospitals often charge uninsured patients the full price for medicines they bought at 340B discounts.[vi, vii]

The 340B program also includes no requirements to protect patients from aggressive debt collection. One analysis of 75 of the largest 340B hospitals' patient assistance policies found only six of those hospitals prohibited the use of extraordinary collections actions, which can include liens and foreclosures.[viii] Another recent analysis compiled some alarming data about the number of hospitals in the United States that use predatory billing practices – not surprisingly, many of these hospitals participate in 340B.[ix]

Evidence also suggests that these profit incentives influence prescribing practices at 340B hospitals (which must be non-profit), contributing to higher patient out-of-pocket costs. For example, GAO shows Medicare has higher spending on outpatient medicines at 340B hospitals, meaning patients at these hospitals are prescribed more medicines or more expensive medicines.[x] A similar study of patients with commercial insurance found that the average cost per outpatient prescription was more than 150% greater at 340B hospitals as compared to non-340B hospitals.[xi, xii]

In addition to these prescribing patterns, other studies have found 340B creates incentives for more provider consolidation, which drives up health care costs. As demonstrated by the recent *New York Times* investigation, by acquiring smaller non-340B hospitals or buying up independent physician practices, 340B hospitals can increase the reach of the program and buy more medicines at the discounted 340B price—enabling them to generate even more revenue. Often these newly acquired physician offices are in wealthier areas than the 340B hospital.[xiii] Yet, research shows the "financial gains for [340B] hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients."[xiv]

The 340B program today does not resemble the program created in 1992.

Due in large part to the profit motives of large hospital networks and for-profit corporations, the 340B program has experienced tremendous growth. 340B is now the second largest federal prescription drug program, behind only Medicare Part D, exceeding Part B, Medicaid and VA/TRICARE/DOD.[xv] From 2014 to 2021, the 340B program grew from $9 billion to $44 billion in sales at the 340B discounted price.[xvi] It more than doubled from 2017 to 2021 alone – without any legislative action by Congress. Yet there is no evidence that this growth has been accompanied by increased patient benefit.

To make matters worse, 340B has also been exploited by for-profit chain pharmacies. These pharmacies contract with 340B hospitals and clinics to dispense the medicines prescribed by those entities. Under guidance issued by the Health Resource and Services Administration (HRSA) these pharmacies are considered "contract pharmacies." Large chain pharmacies, like CVS and Walgreens, account for 75% of these

contract pharmacy arrangements, the number of which has grown 5,000% since 2010.[xvii] 340B hospitals and clinics and their contract pharmacies generated an estimated $13 billion in gross profits on 340B medicines sold through contract pharmacies in 2018.[xviii] Despite these massive profits, there are no requirements that patients benefit. GAO found the majority of 340B hospitals surveyed reported they did not share discounts with patients at their contract pharmacies.[xix] A new analysis of contract pharmacy claims found that most patients received "zero or close to zero" in 340B discounts.[xx]

The program needs to be fixed to put patients first.

It is important that 340B discounts are used to help vulnerable patients, not pocketed by hospitals and pharmacies that do little to help patients afford their medicines. The following policies could help ensure the program serves the vulnerable patients it was intended to help.

- **Patient Affordability:** Changes should be made to ensure more patients benefit from the discounts provided by manufacturers. This includes a sliding fee-scale that requires hospitals to share discounts with low-income and uninsured patients.
- **Patient Definition:** 340B hospitals and clinics are only permitted to use drugs purchased at 340B discounts for individuals who meet the definition of patient under the 340B program. But the GAO and OIG have stated that the HRSA guidance does not clearly define the term "patient" for the purposes of the program.[xxi, xxii] A clearer definition is needed to ensure xneedy patients are benefiting from 340B, not hospitals and for-profit pharmacies.
- **Transparency in the System:** The 340B program is a black box with no line of sight into how much hospitals are making from the program and what types of patients are receiving medicines that qualify for 340B discounts. Policymakers should implement commonsense transparency requirements so that we understand how much hospitals are making money from the program.
- **Hospital Eligibility:** Making sure needy patients are benefiting is also contingent on ensuring true safety-net hospitals in vulnerable communities are the ones participating in the program. The DSH metric is currently the only quantitative metric used for 340B hospital eligibility and is inadequate for that purpose, because (1) it is an inpatient metric (whereas 340B is an outpatient drug program) and (2) it also does not capture care provided to uninsured patients or charity care. To help better target the 340B program, a minimum charity care threshold should be added as another hospital eligibility criterion. Additionally, the eligibility standards for nongovernmental hospitals should be strengthened and enforced. A GAO report found it is likely there are nongovernmental hospitals participating in 340B that are not eligible for the program.[xxiii] Policymakers need to enforce and strengthen the hospital eligibility requirements to ensure the appropriate hospitals are participating.
- **Outpatient Clinic Eligibility:** Unfortunately, there is evidence that 340B hospitals are expanding their outpatient care into more affluent areas through outpatient clinics designed to generate profits by obtaining 340B discounts on medicines prescribed to privately insured patients at these clinics.[xxiv] New eligibility rules are needed so that only true safety-net outpatient clinics of a 340B hospital providing a broad range of services (not just infusions) may purchase drugs at 340B discounts.
- **Program Integrity:** As recently as December 2020, GAO found that for HRSA audits in FY 2012-2019, there were more than 1,500 findings of covered entities not complying with 340B requirements. Increased oversight is needed to ensure the 340B program benefits vulnerable or uninsured patients, and that program requirements are being met.
- **Contract Pharmacies:** Despite the fact "contract pharmacies" is not mentioned anywhere in the 340B statute, HRSA guidance has allowed contractual arrangements between for-profit pharmacies and 340B hospitals to explode in recent years. This growth has led to contract pharmacies becoming a profit center for pharmacy chains, with no evidence that patients are consistently benefiting. While the courts consider the role of contract pharmacies in the program, Congress should turn its attention to examining how the program has failed patients.

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