Preserving the 340B Program and Protecting the Safety Net

As we continue to fight a global pandemic, it is more important than ever that policymakers ensure federal programs like the 340B drug discount program are benefiting vulnerable patients and underserved communities, including the same communities COVID-19 has disproportionately impacted. Congress originally created the 340B program to help vulnerable patients access medicines at safety-net hospitals and certain clinics. After nearly three decades, the program no longer resembles that original Congressional intent. Today, the 340B program has largely evolved in ways that leave patients behind, and instead financially benefit large hospital systems, for-profit pharmacies and other middlemen.

It is unclear if patients are in fact benefiting from the program today.

Unfortunately, despite pharmaceutical manufacturers paying more and more money in 340B discounts, there is no evidence that this growth in 340B translates into lower costs for patients taking prescription medicines. A recent hospital index released by the Lown Institute found that the 10 nonprofit hospitals that spend the least on charity care and community investment compared to the value of their tax exemptions are all 340B hospitals.[i] 340B is intended to be a safety-net program, so there is a big disconnect if participating hospitals are also providing the lowest levels of charity care to our communities while benefiting from both the 340B program and tax breaks.

Serious lack of program oversight and accountability have contributed to the program failing patients. Part of the problem is there are no requirements for how hospitals participating in the program use revenue from 340B to help needy patients. In fact, both the Government Accountability Office and Office of Inspector General have found that 340B hospitals often charge uninsured patients the full price for medicines for which the hospital received a 340B discount.[ii,iii] And despite a broad range of stakeholders raising concerns that patients are not always benefiting, the Health Resources and Services Administration (HRSA) has not created a clearer definition of a 340B patient to ensure hospitals more accurately identify patients for whom 340B discounts apply. HRSA has also shied away from holding 340B covered entities accountable – sometimes even failing to enforce basic eligibility requirements. The agency is essentially turning a blind eye, letting 340B covered entities profit from 340B without ensuring they meet basic program standards – all at the expense of needy patients who could benefit from manufacturers' steeply discounted medicines.

Evidence also suggests profit incentives driven by the 340B program are distorting the entire health care market and increasing health care costs for everyone. An independent analysis by Rena Conti published in the *New England Journal of Medicine* (NEJM) came to the same conclusion, finding that the scope of 340B is so broad for commonly infused or injected medicines that it's likely raising prices for all consumers.[iv] And alarmingly, another analysis in NEJM concluded that the "financial gains for [340B] hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients."[v]

As a result of the opportunity for profit, the 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.[vi] From 2014 to 2020, the 340B program grew from $9 billion in sales at the 340B price to $38 billion in sales at the 340B price.[vii]

While some 340B covered entities are true safety-net facilities and reinvest the money into care for vulnerable populations, many are not. In fact, we also see a concerning number of 340B hospitals that engage in aggressive debt collection practices or use excess revenue to expand overseas while continuing to reap profits from 340B.[viii] A recent analysis by Johns Hopkins 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]

340B covered entities and for-profit pharmacies have co-opted the program.

The current 340B program is financially attractive to large hospital systems and for-profit pharmacies because these entities can manipulate the program to benefit their bottom line often without a commensurate benefit for patients. Today, large hospitals buy deeply discounted 340B medicines and then turn around and charge higher prices for both uninsured patients and patients with commercial insurance. Hospitals then pocket the difference with no strings attached; additionally, hospitals have no requirement to use that profit to help patients. The difference between what the hospitals pay and what they charge patients and insurance companies is significant. One study found that commercial insurance reimburses 340B hospitals on average three times what they pay for physician-administered medicines[x]—this translates into higher cost sharing for many patients.

To make matters worse, what is supposed to be a nonprofit program has been flooded by for-profit chain pharmacies like CVS, Walgreens and Walmart. These pharmacies help large hospitals and other covered entities further increase their 340B generated revenue through "contract pharmacy arrangements" – without any congressional approval and despite there being no mention of "contract pharmacies" in the original 340B statute. 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B retail medicines in 2018.[xi]

Reforms to the program are needed to put patients first and get the program back on solid footing.

It is important that 340B discounts be used to help patients, not pocketed by covered entities and pharmacies that do little to help patients afford their medicines. But the archaic rules of the 340B program do not ensure that it serves the vulnerable patients it was intended to help. It no longer even resembles a true safety-net program. Biopharmaceutical companies are advocating for meaningful improvements to ensure more patients directly benefit from the discounts that manufacturers provide. Part of that is ensuring covered entities are held accountable for how they use 340B discounts, rather than simply using the money for any purpose without question or reporting requirements. This must be addressed.

Additionally, under the 340B statute, covered entities are only permitted to use 340B discounts for individuals who meet the definition of patient under the 340B program, but currently there is a lack of clarity around who qualifies as a 340B patient. This raises concerns with covered entity compliance with program requirements and broader integrity of the program.

The 340B program should be put back on track so that it more directly benefits vulnerable patients. The program's intent has always been to help patients. Biopharmaceutical companies support common-sense updates to the 340B program that help vulnerable patients instead of allowing the program to serve as a revenue-maximizing enterprise for hospitals, contract pharmacies, or other for-profit entities. Policymakers should pursue changes that increase accountability and transparency in 340B. If the program worked as originally intended, it could be a true safety net for vulnerable and uninsured patients.

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vi Berkeley Research Group. Measuring the Relative Size of the 340B Program: 2018 Update. June 2020.
vii A Fein, The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019, June 2021.
viii J. Rau. Hemmed In at Home, Nonprofit Hospitals Look for Profits Abroad. June 22, 2021. Kaiser Health News.
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