340B—Where Do We Go From Here?

For 30 years, the 340B program, administered by the US Health Resources and Services Administration (HRSA), has allowed community health centers, hospitals caring for a disproportionate share of low-income patients (DSH), and other clinics serving low-income individuals to receive discounts for outpatient drugs. These organizations receive the list price reimbursement of drugs for insured patients, with the goal of passing savings to patients and reinvesting in programs that allow them to "stretch federal resources as far as possible."

While 340B can help safety-net clinics stay afloat, concerns that it has outgrown its mission have led to controversy. The primary criticism of 340B has been its rapid growth. The number of covered entities or eligible health care facilities has more than quintupled in the past 2 decades. While the Affordable Care Act (ACA) did expand opportunities to qualify for 340B status, the increase has been driven mostly by an uptick in DSH hospitals. The ACA also allowed 340B entities to obtain discounted drugs from an unlimited number of contract pharmacies with the goal of expanding the reach of the program and allowing health care facilities and patients more flexibility. These dispensaries, mostly part of for-profit retail chains, could receive a cut of the savings flowing to health care facilities and thus grow quickly. Since these pharmacies were not housed within covered entities, discounts could also be diverted to people who were not patients of a particular 340B site. As a result of these drivers, the total amount of 340B discounted drug purchases rose from roughly $2.4 billion in 2005 to $38 billion in 2020, accounting for approximately 7% of drug spending.1

Others argue savings are not flowing to where they are most needed. Research suggests that hospitals do not spend more on uncompensated care after enrolling in the 340B program, and that hospitals that joined in the later waves of the program were more likely to serve wealthier areas with higher rates of private insurance.2,3 Moreover, not all covered entities ensure that their patients receive discounted prices if they fill a prescription at a contract pharmacy.

Finally, 340B may be perpetuating inefficiency. Scholars note the program’s awkward incentives could lead to higher health spending if sites prefer using branded products over generics (since there are greater discounts for higher cost treatments) and this affects non-340B practice patterns.4

Manufacturers and payors have started to resist. Multiple pharmaceutical companies attempted to restrict distribution to contract pharmacies resulting in a cascade of lawsuits; while an appellate court recently sided in the companies’ favor, other appeals are pending, and for now, 340B entities can still partner with these pharmacies.5 In its capacity as a large insurer, the federal government tried to reduce Medicare reimbursements to 340B facilities, arguing they did not require such generous payments for medications if they obtained them at significantly discounted rates. However, this also resulted in a legal challenge, and the change was ultimately reversed by the US Supreme Court.6

While 340B has escaped these challenges, it seems clear that something must change. Some have argued the program is just too complicated to continue and should either be shrunk significantly or simply scrapped. This would be a mistake. While 340B is flawed and inelegant, its patchwork of subsidies helps patients with low income receive the standard of care that might otherwise be out of reach. As just 1 example, 340B helped a safety-net health system invest in a primary-care model to cure hepatitis C—an urgent public health priority—that may have otherwise been cost prohibitive.7 A similar calculus can apply to clinicians helping low-income patients gain access to novel medications for diabetes, heart disease, HIV, and beyond.

Until we enact an insurance system that reimburses health care facilities equitably, regardless of their patients’ socioeconomic status, the program must be preserved as a matter of moral clarity. Yet, we should consider reforms that realign 340B with its core mission of bolstering the safety net. We suggest focusing on 3 goals: improving oversight, reimagining eligibility, and strengthening protections for facilities and patients.

First, there is little accounting as to whether 340B discounts are passed on to patients. While the government has conducted audits only on a fraction of entities, a majority of these examinations flagged compliance issues related to eligibility, diversion of drugs to ineligible patients, and duplicate discounts with Medicaid programs.8 Though the ACA gave the HRSA the ability to sanction organizations that violate program requirements, the agency does not clearly have the ability to oversee other aspects such as defining which patients are eligible to receive discounted medications. Reform could add reporting requirements, expand the use of audits, and allow the Office of Pharmacy Affairs (a division within HRSA tasked with administering 340B)
to explicitly have full authority over the program regarding the use of contract pharmacies, hospital and patient eligibility, and broader operations.1

Second, reform could redesign hospital eligibility to ensure only those serving patients with low income qualify and slow the growth in DSH hospitaling the program. Hospitals currently need a DSH share greater than 11.75%, which is calculated by proportions of Medicare and Medicaid days out of total inpatient days, to join the program. This metric has limitations as it does not reflect the fraction of care devoted to uninsured patients—-a key group the 340B program aims to serve.

HRSA could alter which hospitals actually qualify for 340B by reimagining which hospitals constitute the safety net. Raising the DSH adjustment percentage would narrow eligibility, but that is a blunt instrument and it is not recommended. Instead, safety-net hospitals could be redefined on a continuum based on multiple factors, including DSH adjustment, measures of uncompensated care, and area socioeconomic disadvantage as other scholars have proposed.9 Based on these definitions, 340B discounts could be targeted better ensure 340B benefits are targeted toward people with the most need.

Third, reforms to the 340B program should protect low-income patients and safety-net organizations. For example, a provision of the ACA prevented new 340B organizations from receiving discounts on drugs designed to treat rare diseases in order to encourage pharmaceutical innovation for rare diseases. However, this can undermine access to these drugs by low-income patients since reduced prices are not available and is increasingly relevant as these drugs account for higher shares of overall drug spending. This feature could be reversed.

Reforms could also ensure 340B organizations are not overcharged. While HRSA can calculate the ceiling price of a drug (the maximum price that a manufacturer could charge a covered entity), clinicians and health care facilities historically did not have access to this information and could not pursue penalties against drug companies for charging above this price. As of 2019, there is now a database of ceiling prices; reform could ensure further price transparency and allow HRSA to pursue more aggressive sanctions against manufacturers found to overcharge for their products.

Lastly, changes to 340B should be accompanied by reforms that decrease the need for the program to exist, such as greater federal incentives to expand Medicaid and strengthening of public sector drug price negotiation authority.

The 340B program has helped people in the US with the most economic disadvantage receive medications, and it has bolstered the safety net for decades. Instead of heeding calls to cancel the program amid growth, policymakers should consider reforms that better ensure 340B benefits are targeted toward people with the most need. It is the least patients, clinicians, and health care facilities deserve.

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