Enacted by the US Congress in 1992 to help entities serving lower-income and uninsured patients stretch their resources, the 340B Drug Pricing Program mandated drug companies give large discounts to covered entities (CEs). Judging the program on its outcomes, not its intentions, there is growing evidence that the 340B program fails to achieve its primary goal. Giving discounts to entities, rather than to patients, primarily shifts resources from payers and drug companies to large hospital conglomerates. Hospitals have no requirement to disclose which patients receive the drugs and how resale profits are used. A program originally created to assist a small number of hospitals has now exploded, covering thousands of CEs and generating billions of dollars. This growth is fueled by the program design, which allows CEs to keep the difference between a drug’s full costs and the 340B program price discount, which can exceed 50% of list price.

Problematically, the legislation lacks rules about how CEs use their revenue from the program. A 2021 study found no evidence that hospitals entering the 340B program increased their care for underserved populations any more than institutions not participating in the program—the core justification for receiving the discounts. Another study showed hospitals exhibit strategic corporate behavior to meet, without exceeding, the minimum share of low-income patients to qualify for the 340B program. Further data suggest that participating hospitals devote fewer resources (1.7% of net patient revenues) toward charitable care than the average hospital (2.0%).

340B hospitals are expanding in wealthier neighborhoods by acquiring clinics (child sites), which gain the CE designation of the parent hospital. In these areas, 340B institutions can generate greater returns by delivering drugs to a largely insured population. A similar trend is evident with respect to the contract pharmacies, as retail pharmacies participating in the 340B program favor high-income neighborhoods and avoid disadvantaged neighborhoods. Since 2010, the number of 340B CEs grew by 50%, while contract pharmacies have expanded 25-fold. This has paralleled growth in 340B drug purchasing, which has grown approximately 24% annually from 2015 to 2021. 340B hospitals earned a 37% net income (or excess of revenues over costs for nonprofit hospitals) premium compared with the average hospital. While not a problem per se, these revenues are rents that are not reinvested in underserved populations.

The design of the 340B program imposes costs on the broader health care system. The discounts are not passed on to patients, who pay copays based on the list price, not the discounted purchase price. The 340B program also incentivizes the use of higher-cost medicines—the same percentage discount applied to a higher-priced drug raises more revenue for the institution (regardless of payer). An analysis by the US Government Accountability Office found that per-beneficiary Medicare Part B drug spending was higher at 340B hospitals compared with institutions not participating in the program. Medicare reimburses all inpatient medications at 106% of average sale price, allowing CEs to generate significant revenue from Medicare. This potential for 340B revenue from public and private payers has led to increased consolidation in the cancer care sector, further increasing costs of care.

There are ample opportunities to reform the 340B program that will fulfill the broader vision of improving health care access while mitigating the program's current problems. First, reforms must increase transparency. The Health Resources and Services Administration (HRSA), which oversees the 340B program, should require that CEs report how they are using the 340B revenues, how much the institution is earning, how those earnings are being reinvested into patient care, and how the revenues benefit low-income patients specifically. All drugs purchased under the 340B program...
should be marked as such in transactions with all payers. Reimbursements for those medications must be reported as well. This transparency is a minimum reform needed, as it will allow independent agencies to monitor the program.

Second, better oversight is needed to ensure program integrity, prevent diversion of discounted drugs, and increase fiscal responsibility. HRSA should conduct regular audits, investigate potential abuses, and impose penalties for noncompliance. Annual recertification for hospitals and their affiliates participating in the Disproportionate Share Hospitals payment program would ensure that these institutions are maintaining their mission in treating underserved populations. While this would still leave the door open for creative accounting, the transparency rules would give the public access to these data. In addition, Congress should ask the Office of Inspector General to issue a report covering program compliance and integrity, financial impact on both CEs and drug manufacturers, contract pharmacies, and patient benefit. If CEs are following the intent of the program, this will not decrease access to medications for low-income patients. Rural and critical access hospitals (which are reimbursed at cost) can be exempt from these measures.

This will add a small administrative burden. Accounting departments can report if the drug was purchased under the 340B program and the purchase/resale prices. Tracking where excess revenue is spent is similarly a small ask given the large revenue the 340B program generates for hospitals.

Third, Congress must narrow the scale and scope of the contract pharmacy arrangements and cap the number of arrangements. Any new contract pharmacy location should be limited to low-income areas that serve the 340B program’s intended population. If the discount is to follow the institution, Congress must define what it means for an individual to be a patient of that institution, as this is currently a contentious topic.10

Congress should consider overhauling the program so that the 340B discount follows the beneficiary, like other social benefits, instead of leaving the door open for large institutions to game the program. This could be accomplished in a variety of ways, such as CE accounting (where the purchase and resale price are recorded for each individual sale along with reporting if the drug was a 340B program purchase) with reporting to appropriate state and federal authorities. This will help avoid duplicate discounts with the Medicaid Drug Rebate Program. Because of the interaction of 340B program with the Medicaid Drug Rebate Program, which provides discounts for drugs purchased by state Medicaid programs, we favor reporting regulations initiated at the state level, allowing more local control of the process. However, Congress must also clearly define which patients are eligible for the 340B program. This would fully designate who would qualify for the discount. If the discount follows the patient, it should also transfer to investor-owned hospitals, providing incentive for those institutions to care for underserved populations. Even limiting the discount to low-income patients leaves revenue for institutions from Medicaid Managed Care Plans, dual-eligible patients, and patients with private insurance if the definition of low-income patient includes low-wage earners.

Members of Congress, realizing the shortcomings of the 340B program, have recently proposed the bipartisan SUSTAIN 340B Act. This act authorizes the Secretary of the Department of Health and Human Services to perform audits on CEs, along with their contract pharmacies and child sites. It would authorize audits of manufacturers and monetary penalties if they refuse to deliver drugs under the program. It also defines contract pharmacies and requires CEs register those arrangements with the Department of Health and Human Services. It is a good first step, adding some much-needed transparency and HRSA authority. There is still much work to be done. The bill does little else to curb 340B growth—codifying the expansion of child sites and contract pharmacies and failing to define a patient. These and other fundamental reforms that focus the program on its original purpose can ensure the 340B program helps low-income patients without unintended consequences.