

UNDERSTANDING THE 340B PROGRAM

Congress created the 340B Drug Pricing Program to help vulnerable patients access medicines at safety-net hospitals and certain clinics. Under the program, manufacturers are required to provide steep, mandatory discounts on outpatient medicines to federal grantees and safety-net hospitals serving large numbers of uninsured or otherwise vulnerable patients. Nearly three decades later, the program no longer resembles its original mission, with little to no evidence patients are always benefiting.

QUICK FACTS ABOUT THE 340B PROGRAM

40%

40% of all hospitals in the United States participate in the 340B program.

63%

63% of hospitals that receive 340B discounts have charity care rates below the 2.7% national average for all hospitals.

\$13B

\$13 billion in estimated gross profits was generated by 340B covered entities and their contract pharmacies on 340B retail medicines in 2018 alone.

PUTTING THE 340B PROGRAM BACK ON SOLID FOOTING BY STOPPING PROGRAM ABUSES AND ENSURING IT BENEFITS PATIENTS

The 340B program is now the second largest federal prescription drug program, behind only Medicare Part D. The current 340B program attracts entities and for-profit pharmacies because lax program rules enable them to manipulate the program to benefit their bottom lines, often to the detriment of patients. Biopharmaceutical companies, on the other hand, are advocating for meaningful improvements that can be made to ensure patients benefit more directly from the discounts provided by manufacturers and that covered entities are held accountable for how they use 340B discounts.

PATIENT AFFORDABILITY

Data indicate that many 340B hospitals may be increasing out-of-pocket costs for patients, leaving patients to pay the full price for their medicines despite the discounted price the hospitals receive. Similarly, needy, uninsured patients who show up at 340B hospitals' contract pharmacies don't always benefit from the discounted price. Changes should be made to ensure patients more directly benefit from the discounts provided by manufacturers.

PATIENT DEFINITION

Covered entities are only permitted to use 340B discounts for individuals who meet the definition of patient under the 340B program. But the Government Accountability Office (GAO) and Office of Inspector General have stated that the Health Resources and Services Administration's (HRSA) guidance does not clearly define the term "patient" for the purposes of the 340B program. A clear definition is needed to ensure needy patients are truly benefiting from 340B, not hospitals and for-profit pharmacies.

TRANSPARENCY IN THE PROGRAM

The 340B program generates billions in profits for hospitals, pharmacy chains and other entities, siphoning resources away from patients. There are no requirements for how 340B hospitals must use 340B discounts to help patients, and they consistently oppose any proposals that would require them to show how much in discounts they receive from 340B and how the money is used. Policymakers should implement common-sense transparency requirements so that 340B patients are reaping the benefits of the program.

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 noncompliance by covered entities with 340B requirements. A separate GAO report found it is likely nongovernmental hospitals are participating in 340B that are not even eligible for the program. Increased government oversight is needed to ensure the 340B program directly benefits vulnerable or uninsured patients, while at the same time certifying program requirements mandated in the statute are being met.

CONTRACT PHARMACIES

Since 2010, there has been a 4,000% increase of contract pharmacies in the 340B program. These pharmacies help enable large hospitals to 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. The contract pharmacy policy should be reconsidered as part of broader efforts to ensure patients have access to affordable medicines at 340B providers.