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340B 101

By Jackson Hammond

Enacted in 1992 to enable a small number of safety-net hospitals to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," the 340B Drug Pricing Program has morphed into the second-largest drug pricing program in the country after Medicare Part D. The 340B Program mandates that pharmaceutical manufacturers provide discounts on prescription drugs to qualifying health care entities in order to subsidize those entities that provide care to the most vulnerable populations. However, the 340B Program is broken and leads participating entities to invest their cost savings in wealthier communities at the expense of poorer ones while simultaneously contributing to increased drug prices, consolidation in the health care system, and government costs. These problems result from a lack of statutory requirements for how hospitals must use 340B savings or even monitor how the savings are used and little authority for oversight by the Health Resources and Services Administration (HRSA), the agency responsible for the 340B Program. Once applicable to fewer than 500 covered entities (CEs), the program now consists of nearly 13,000 CEs, including hospitals, federally qualified health centers (FQHCs), and nearly 30,000 contract pharmacies.[1] This growth has further fueled the problems with the 340B Program, increasing consolidation, drug prices, and costs to taxpayers.

KEY TAKEAWAYS

The 340B Program requires pharmaceutical manufacturers to provide discounts to certain safety-net providers to help subsidize care to vulnerable populations and "stretch scarce federal resources as far as possible."

Over the life of the program, and particularly in the last 15 years, the number of participating providers has dramatically expanded. This expansion has increased provider consolidation, drug prices, and costs to states and the federal government, all while worsening access to care for low-income patients. The lack of transparency in the program has made these issues harder to combat.

To mitigate these problems, participating providers should be required to reveal how much in savings the 340B Program generates and what specific operations they go toward. Congress should look to narrow program participants to only those that can demonstrate that they are providing a tangible benefit to safety-net populations.

Program Origins

The 340B Program originated as an unintended consequence of the Medicaid Drug Rebate Program (MDRP). Enacted in 1990, the MDRP requires Medicaid to receive the lowest price of any customer, i.e. the Medicaid best price—and requires that pharmaceutical companies participate in the MDRP in order to bill the Medicare, Medicaid, and Veterans Affairs health programs. Previously, pharmaceutical manufacturers voluntarily provided free or significantly reduced-priced drugs to select safety-net nonprofit hospitals. However, post-MDRP, this meant Medicaid would receive these heavily discounted prices. In response, manufacturers stopped donating drugs to safety-net hospitals.[2]

Congress then passed the Public Health Service Act in 1992. Section 340B of the law conditioned manufacturer participation in Medicare and Medicaid on providing qualifying hospitals and other providers with discounted drugs. Originally applicable only to drugs sold by a few hundred CEs in the mid-1990s, the 340B Program has grown to apply to most nonprofit hospitals in the country, as well as their child sites, which include off-site clinics, departments, and services.

Program Design

Discount Requirements

The 340B Program's discounts apply to specified outpatient drugs (namely, outpatient prescription drugs and biologics, excluding vaccines and orphan drugs) with a maximum price applied to each drug, known as the ceiling price. The ceiling price is calculated as the average manufacturer price (AMP, or the average price a group purchasing organization pays the manufacturer) minus the unit rebate amount (the money manufacturers return to Medicaid after the purchase of the drug divided by the AMP), times the size of the particular drug package.

Total purchases for 340B-discounted drugs were $53.7 billion in 2022, whereas the measured list price value was around $106 billion.[3] Individual discounts per drug are difficult to establish due to poor transparency, but estimates range between 22.5 percent to over 50 percent of the average sales price, with some drugs being priced at $0.01 for CEs.[4] State Medicaid programs and CEs may not claim Medicaid rebates for drugs purchased under 340B, though there is evidence that these "duplicate discounts" still take place.[5] CEs are prohibited from giving 340B-discounted drugs to non-qualifying patients, though the definition of *qualifying patient* (see below) is so vague it can apply to virtually anyone receiving care at the CE.

Covered Entities

CEs include Disproportionate Share Hospitals (DSHs), children's hospitals, freestanding cancer hospitals, sole community hospitals, FQHCs, rural referral centers, and Critical Access Hospitals (CAHs). Around 90 percent of CEs are either DSHs or CAHs.[6] The number of CEs has grown exponentially, increasing from 2,424 CEs in 2005 to 12,279 CEs and 34,840 contract pharmacies in 2024. To qualify as CEs, all eligible entities except for CAHs must meet a minimum DSH adjustment percentage (the percentage of low-income Medicare and Medicaid inpatient days) of either 8 percent or 11.75 percent, depending on the entity type.[7] CEs can receive discounts for drugs administered at all registered child sites regardless of whether indigent populations are served.

Contract Pharmacies

CEs contract with pharmacies to provide drugs to their patients. Originally, each CE was allowed to contract with only a single off-site pharmacy if it did not have a pharmacy on site. However, in 2010, HRSA promulgated a rule allowing virtually unlimited contract pharmacies for any CE. As such, the number of contract pharmacies skyrocketed from 254 in 2010 to more than 32,500 in 2024.[8] Contract pharmacy agreements have also expanded geographically, with most CEs contracting with pharmacies in numerous states beyond where they or their child sites are.[9]

Pharmaceutical Manufacturers

While it is not legally mandated, drug manufacturers have strong federal incentives to join the 340B Program in order to receive payment from Medicare and Medicaid. To have their drugs covered by both programs, they must participate in the MDRP, which requires discounts to 340B CEs. Recently, manufacturers began restricting discounts to CEs with multiple contract pharmacies in response to 340B's growth and concerns about duplicate discounts and drug diversion. HRSA and CEs have contested these limits, which are now under judicial review.[10]

Patients

The 340B statute vaguely defines *eligible patients* as those who have established relationships with the CEs that maintain their medical records and receive care from providers affiliated with said CEs. FQHCs and similar types of providers qualify patients by ensuring that they receive grant-funded services.[11] In practice, any patient at a 340B CE is considered eligible regardless of income or care need. It is important to note that 340B entities are not required to offer discounted prices or use savings for uninsured care.

Problems

Transparency

Lack of transparency about the prices CEs obtain for drugs, revenue generated from discounts, and how savings are spent undermine confidence in 340B and whether it adheres to its original intent. There are serious concerns that the 340B Program is not providing value to underserved patients, particularly as contract pharmacies have expanded footprints in wealthier areas while simultaneously decreasing services and care access in poorer areas.[12]

Nonprofit hospitals in general (a requirement for 340B eligibility) have lower overall percentages of revenue going toward charity care than for-profit hospitals do, and there is little data to substantiate the claim that 340B revenues are used primarily to provide care for the uninsured or indigent.[13]

The lack of program reporting requirements makes detecting CEs receiving illegal duplicate discounts extremely difficult. Duplicate discounts directly increase costs to the states and federal government. The Government Accountability Office (GAO) has observed that HRSA does little to prevent or require repayment for duplicate discounts.[14]

The 340B Program has few statutory reporting requirements, and current regulations shield CE discounts from the public eye. The involvement of tens of thousands of contract pharmacies makes the program opaque, leading to rampant program violations. A 2020 GAO report noted a total of 1,536 violations of the 340B rules from 1,241 audits HRSA conducted between fiscal years 2012 and 2019.[15]

Program Size

The rapid growth of the 340B Program directly impacts prescription drug market dynamics. There is increasing evidence that CEs are incentivized to choose more expensive drugs to receive larger discounts — and thus profits — when CEs resell them.[16] Uninsured patients are hit hardest by having to pay higher prices. But even insured patients pay more in copays for drugs, which are typically based on the list price. A 2018 GAO report found that 30 of 55 audited CEs reported passing some or all the discounts to patients.[17] However, a study by IQVIA found that virtually no patients using cash, insurance, or Medicare received discounts.[18]

Medicare Part B pays full price (average sales price plus 6 percent) and beneficiaries pay full coinsurance for drugs that are heavily discounted for the CEs.[19] More CEs and contract pharmacies in the program mean excessive Medicare payments and thus costs to taxpayers. The program's size also makes it harder for HRSA to audit CEs for any wrongdoing, such as obtaining duplicate discounts.

Because 340B Program benefits extend to all entities owned by a given CE, the program leads hospitals and other CEs to buy up providers to bring in more revenue, increasing market concentration. As a result, providers who serve wealthier, well-insured patients receive 340B status after being purchased by CEs.[20]

Solutions

The first step to ensuring that the 340B Program is adhering to its original intent is requiring program transparency. CEs should be required to reveal how much in savings the 340B Program generates and what specific operations they go toward. As Congress and HRSA gain a greater understanding of how 340B dollars are being used, they should look to narrow program participants to only those that can demonstrate that they are providing a tangible benefit to safety-net populations.

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