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Overview of the 340B Drug Discount Program

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Congress established the 340B Drug Discount Program in Section 340B of the Public Health Service Act (42 U.S.C. §256b) through the Veteran's Health Care Act of 1992 (P.L. 102-585) to enable certain safety net health care providers ("covered entities") that serve low-income and uninsured patients to purchase drugs at discounted prices. The 340B statute requires manufacturers to offer these covered entities certain covered outpatient drugs (CODs) at discounted prices as a condition of their participation in the Medicaid and Medicare programs. The Health Resources & Services Administration (HRSA), part of the U.S. Department of Health and Human Services (HHS), administers the program. The scale of the program has increased from less than 30,000 registered sites in 2014 to over 60,000 in February 2025. In 2025, covered entities made approximately $100 billion in COD purchases through the program. The program's growth has sparked congressional debate over its scope and HRSA's authority to regulate it.

340B Program Discount and Participants

The 340B statute requires the HHS Secretary to enter into purchase price agreements with drug manufacturers as a condition of their products' coverage under Medicaid and Medicare Part B. The terms of these agreements require manufacturers to sell CODs to covered entities at a "ceiling price," calculated based on a statutory formula derived from the rebate formulas under the Medicaid Drug Rebate Program (MDRP). Manufacturers may not charge covered entities more than the ceiling price if they sell the drug to any other purchaser at any price, although covered entities may be able to negotiate sub-ceiling price discounts.

The providers that qualify as covered entities are listed in the 340B statute and include federal grantees such as Federally Qualified Health Centers, Tribal and Urban Indian Organizations, Ryan White HIV/AIDS Program grantees, and other types of health centers and specialized clinics. Certain hospitals are also eligible for the program, including Critical Access Hospitals, children's hospitals, free-standing cancer hospitals, and disproportionate share hospitals (DSHs). DSHs, and most other hospitals, must meet certain disproportionate share thresholds to participate in the program. As of 2023, a majority of participating 340B-covered entities were hospitals and their outpatient clinics that qualified as child sites.

340B Program Revenue

Apart from the post-sale rebates received by AIDS Drug Assistance Programs (ADAPs), almost all CODs are purchased by covered entities at or below the 340B ceiling price as a discount. Covered entities can then dispense CODs to eligible patients, either through in-house pharmacies or contract pharmacies with whom they have contracted to dispense CODs. Covered entities may pass their discounts on to patients, but the statute does not require them to do so. As a result, covered entities may receive reimbursement from payers, such as Medicare and private health insurance, that exceed their acquisition cost. The difference between the covered entities' acquisition costs under the 340B program and their payments upon dispensing CODs is often referred to as *340B revenue* or *340B savings*.

The 340B discount price is confidential, and covered entities are not required by statute to report their revenue under the program. Therefore, there is limited public information on the scale of 340B program revenue. Some states, such as Minnesota and Illinois, have enacted transparency requirements for covered entities. Minnesota's analysis found that covered entities in the state "generated a collective net 340B revenue of at least $1.34 billion for calendar year 2024." Illinois has not yet released reporting.

The Medicare Payment Advisory Commission has estimated that, in 2022, Medicare Fee-for-Service reimbursements to covered entities for CODs were $3.9 billion greater than the cost those covered entities had paid to acquire them. The Centers for Medicare & Medicaid Services (CMS) announced in July 2026 that some covered entities will begin receiving reduced Medicare payments for certain drugs, beginning in 2027, based on the results of their drug acquisition cost survey. A previous effort by CMS to reduce payments to covered entities was overturned by the Supreme Court.

340B Program Compliance

The 340B statute places certain limitations on covered entities to help ensure discounts are appropriately accessed. For example, 340B discounts are prohibited from being received on COD claims for which a rebate is provided under MDRP, a Maximum Fair Price (MFP) is in effect under the Medicare Drug Price Negotiation Program, or a Medicare inflation rebate is invoiced. This is referred to as the *duplicate discount prohibition*. Covered entities are also prohibited from selling CODs to non-patients (known as *diversion*). The statute permits HRSA and manufacturers to audit covered entities to help ensure they meet the requirements for 340B pricing. It also requires HRSA to ensure that both covered entities and manufacturers comply with program requirements.

DSHs, children's hospitals, and free-standing cancer hospitals may not use a group purchasing organization to buy 340B drugs. Instead, these hospitals, along with other covered entities, may purchase drugs through the Prime Vendor Program (PVP), which the 340B statute directs the Secretary to establish to enable the distribution of CODs. Through the PVP, covered entities can aggregate their purchasing power to achieve sub-ceiling discounts. The PVP also maintains the Office of Pharmacy Affairs Information System and provides educational resources to covered entities. Since 2004, the PVP contract has been held by Apexus.

Covered entities that do not comply with statutory requirements risk losing their covered entity status. They are also required to repay drug manufacturers if an audit shows duplicate discounts were received for a 340B drug. Drug manufacturers who are noncompliant with statutory requirements may be subject to civil monetary penalties (CMPs) imposed by HRSA. The agency has also promulgated regulations that govern administrative dispute resolution (ADR) proceedings. Both manufacturers and covered entities may use ADR to resolve disputes related to pricing overcharges and covered entity eligibility.

Rebating of 340B Drugs and Litigation

In recent years, some drug manufacturers have expressed interest in offering the 340B ceiling price as a post-sale rebate, rather than an upfront discount, to give them more control over covered entities' use of 340B pricing. Covered entities have generally opposed this change, arguing that rebate models threaten their 340B savings. In 2024, several manufacturers announced that they would begin implementing 340B rebate models for certain covered entities on a subset of CODs. HRSA responded in a letter to manufacturers that only the HHS Secretary could approve a rebate model and threatened CMPs if manufacturers proceeded to conduct a rebate model without HRSA's approval. Several drug manufacturers then sued HRSA in federal district court, arguing that HRSA lacked the authority to require that manufacturers seek the Secretary's approval before rebating 340B drugs. In 2025, the United States District Court for the District of Columbia ruled in favor of HRSA, holding that the plain language of the 340B statute and specifically the statutory parenthetical "(taking into account any rebate or discount, as determined by the Secretary)" supported HRSA's position that a drug manufacturer could not unilaterally create a rebate model. The court ruled that the best reading of the statute was that Congress granted the HHS Secretary the discretion to determine how the 340B price should be effectuated. The U.S. Court of Appeals for the D.C. Circuit affirmed this ruling in 2026.

In 2025, HRSA announced a rebate pilot program intended to reduce duplicate discounting between 340B discounts and Medicare MFPs. Under the terms of the pilot, the 340B ceiling price would have been available to all covered entities via a rebate. Drug manufacturers had the option to participate in the rebate pilot if they had a COD that was selected for the Medicare Drug Price Negotiation Program for price year 2026. All nine eligible drug manufacturers opted to participate. Before the model went into effect, the American Hospital Association, an industry group representing 340B hospitals, sued HRSA, alleging that the rebate pilot announcement was arbitrary and capricious under the Administrative Procedure Act. In December 2025, days before the pilot was to take effect, a federal district court enjoined the implementation of the rebate pilot, citing several deficiencies in the agency's administrative record. The injunction was upheld by the United States Court of Appeals for the First Circuit. In February 2026, the parties agreed that the rebate pilot notice should be vacated and remanded to the agency. HRSA then issued a request for information, seeking additional input from 340B stakeholders about the potential impacts of a 340B rebate model. The agency received over 2,400 comments.

On August 3, 2026, HRSA announced the relaunch of the rebate pilot. The revised pilot is nearly identical to the original pilot, although it will allow manufacturers with CODS selected for the negotiation program for both price years 2026 and 2027 to apply to participate. This revised pilot is scheduled to begin on January 1, 2027.

Other Recent 340B Litigation

In addition to litigation surrounding the rebating of 340B drugs, drug manufacturers, covered entities, states, and HRSA have engaged in litigation over various other aspects of the program. In summer 2020, several drug manufacturers announced 340B pricing restrictions on covered entities that dispense CODs through contract pharmacies. Manufacturers challenged HRSA's attempts to stop the conditions through the issuing of violation letters. The cases turned on HHS's interpretation of the 340B statute, which is silent on the use of contract pharmacies. After several federal district courts disagreed about whether HRSA could stop manufacturers from restricting contract pharmacy use, at least two federal appellate courts agreed that drug manufacturers may restrict their offers to sell CODs to contract pharmacies. The appellate courts decided that the plain language of the 340B statute, specifically the words *offer* and *purchased by*, in combination with the statute's silence on contract pharmacy use, meant that manufacturers could impose reasonable conditions on their offers to sell 340B drugs.

In the past few years, many drug manufacturers have created policies limiting the sale of CODs to covered entities that distribute those CODs through contract pharmacies. In response, some state legislatures enacted laws to prohibit drug manufacturers from interfering with contracts between covered entities and contract pharmacies or otherwise prevent manufacturers from limiting COD distribution. Many of these laws have been challenged by drug manufacturers in federal courts across the country, and litigation remains ongoing. HRSA has also been sued by covered entities when it has attempted to enforce its patient definition and other requirements related to covered entities.

Legislative Activity in the 119th Congress

The 119th Congress has contemplated many changes to address ongoing legal and policy questions about the 340B program, including whether and to what extent contract pharmacy use should be permitted, whether the 340B price should be effectuated as a rebate or discount, and whether covered entities must turn over claims data to drug manufacturers as a condition of purchasing 340B drugs. Members have also proposed reforms to other aspects of the 340B program, including the patient definition, hospitals' use of child sites, and increased transparency on the scale and use of 340B revenues. Several proposals would also clarify the use of 340B rebates and would increase HRSA's regulatory authority over the program.

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