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Overview of the 340B Drug Discount Program

Congress created the 340B Drug Discount Program (340B) in 1992 through the Veteran's Health Care Act (P.L. 102-585) to enable health care providers that serve low-income and uninsured patients to purchase drugs at lower costs. The Health Resources and Services Administration (HRSA), part of the U.S. Department of Health and Human Services (HHS), administers the Program. HRSA estimates that 340B sales constitute about 7.2% of the overall U.S. drug market and reports that in 2021, total program sales reached approximately $44 billion, an almost 15% increase over 2020. The authorizing statute—Section 340B of the Public Health Service Act (42 U.S.C. § 256b)—requires drug manufacturers that participate in the Medicaid Program to offer certain outpatient drugs to "covered entities" at discounted prices.

Statutory Requirements

The 340B statute requires the Secretary of HHS to enter into purchase price agreements (PPAs) with drug manufacturers that participate in the Medicaid Program. The terms of these PPAs require manufacturers to sell certain covered outpatient drugs at a "ceiling price," which is calculated based on a statutory formula. Manufacturers may not charge covered entities more than the ceiling price if they sell the drug to any other entity at any price. Providers may pass the drug discounts on to patients, but the statute does not require them to do so. The statute provides a list of "covered entities" that may purchase drugs from manufacturers at discounted prices. Covered entities include Federally Qualified Health Centers, Native Hawaiian Health Centers, Tribal and Urban Indian Organizations, children's hospitals, and other providers that care for rural and underserved populations.

According to HRSA, more than 75% of FY2021 340B covered entity purchases were made by disproportionate share hospitals (DSHs). DSHs are statutorily defined in Section 1886(d)(5)(F) of the Social Security Act; they serve a disproportionate number of low-income patients who qualify for Medicare and Medicaid. To qualify for 340B, a DSH must be owned or operated by a state or local government; be a public or private nonprofit corporation that is granted governmental powers by a state or local government; or be a private nonprofit hospital that contracts with a state or local government to provide care for low-income patients who do not qualify for Medicare and Medicaid. The DSH's percentage of low-income patients must also be above certain statutorily defined percentages in order to qualify for 340B.

The 340B statute places limitations on covered entities. Covered entities are prohibited from receiving duplicate discounts on 340B drugs from Medicaid rebates and from dispensing or selling covered drugs to non-patients. The statute permits HRSA and manufacturers to audit covered entities to ensure they meet the requirements for 340B pricing. It also requires HRSA to ensure that both covered entities and manufacturers comply with Program requirements. Participants who are non-compliant may be subject to civil monetary penalties (CMPs). HRSA also promulgated regulations that govern alternative dispute resolution (ADR) proceedings. Both manufacturers and covered entities may use ADR to resolve disputes related to pricing overcharges and covered entity eligibility.

Changes to the 340B Statute

Congress has changed the 340B Program on a number of occasions, most recently via the Consolidated Appropriations Act of 2022 (P.L. 117-103). The 2022 Act allows certain covered entities that were terminated from the 340B Program during the COVID-19 pandemic to be reinstated through December 31, 2022. During the pandemic, DSH percentages changed for some hospitals as patients delayed care and hospitals postponed elective procedures to divert more resources to caring for patients with COVID-19. Qualifying facilities under the 2022 Act include hospitals that were eligible covered entities *prior* to the COVID-19 pandemic, but lost their eligibility due to a decrease in their DSH patient percentage. The temporary eligibility change allows hospitals that would otherwise be disqualified from 340B pricing to remain eligible through the end of 2022. (More information about this waiver and which entities qualify may be found on HRSA's website, https://www.hrsa.gov/.)

Congress also made substantial changes to the 340B Program in 2010 via the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148), which expanded the list of covered entities to include children's hospitals, cancer treatment facilities, critical access hospitals, rural referral centers, and sole community hospitals that have a certain DSH percentage. Hospital participation in the 340B Program has tripled from the time before the ACA's enactment. There are currently more than 53,000 registered 340B sites, which is almost double the number of registered sites in 2014 (28,272).

The ACA further authorized HRSA to improve Program integrity by ensuring manufacturer compliance with ceiling price sales by allowing HRSA to issue regulations regarding the imposition of CMPs for manufacturer and covered entity noncompliance. The ACA also established the ADR process by which manufacturers and covered entities could settle disputes regarding 340B purchases.

GAO Findings and Recommendations

In recent years, the Government Accountability Office (GAO) has undertaken investigations and audits of the

340B Program, making two main recommendations for oversight and improvement. First, GAO recommends that HRSA increase its oversight of covered entities, and particularly DSHs, to ensure they meet program eligibility requirements. Second, GAO suggests that HRSA and the Centers for Medicare & Medicaid (CMS) enhance their oversight of the 340B and Medicaid rebate programs, respectively, to ensure that covered entities are not receiving duplicate discounts on 340B-covered drugs.

In a December 2019 report, GAO found that over two-thirds of covered entities are nongovernmental hospitals that qualify for 340B based on their contracts with state and local governments to provide care for low-income patients ineligible for Medicare and Medicaid. GAO stated there is little oversight of these hospital contracts, and the 340B statute does not require the contracts to detail the scope of care being provided to low-income patients. Upon reviewing 258 hospital contracts, GAO found that the documentation provided by some covered entities was insufficient to demonstrate that the hospital was actually meeting 340B requirements.

In 2020 and 2022, GAO issued a "priority recommendation" to HHS on the perceived need to prevent covered entities from receiving duplicate discounts from Medicaid and 340B. Federal law allows state Medicaid programs to request manufacturer rebates on certain drugs used to treat Medicaid patients, but drugs that are purchased through 340B are not eligible for these rebates. In FY2018, the Medicaid rebates saved states and the federal government approximately $36 billion. A January 2020 GAO report, however, found several holes in CMS' tracking of state policies and procedures regarding the prevention of duplicate discounts. The report reiterated previous 2018 findings that HRSA lacks guidance and audit procedures to police duplicate discounts in Medicaid, particularly for Medicaid managed care.

Recent 340B Litigation

In summer 2020, drug manufacturers began announcing plans to impose 340B discount restrictions on covered entities that purchase 340B medications through contract pharmacies. Covered entities may dispense 340B drugs through in-house pharmacies or contract with outside retail pharmacies to dispense the drugs on their behalf. Many covered entities do not have their own in-house pharmacies, so contracting with outside pharmacies enables them to participate in the Program.

In setting 340B discount restrictions, the manufacturers argued that the increase in the number of contract pharmacies in recent years has led to increased Program fraud and abuse. Some Members of Congress have reacted to the manufacturer-imposed restrictions by urging HHS to take action against the manufacturers. In May 2021, HRSA issued violation letters to several manufacturers notifying them that the restrictions imposed on covered entities using contract pharmacies violated the 340B statute. The violation letters threatened CMPs for manufacturers that continued their pricing restrictions.

The manufacturers have since challenged the violation letters in four federal district courts across the country, arguing they violate the Administrative Procedure Act and constitute an unconstitutional taking under the Fifth Amendment. The cases turn on HHS's interpretation of the 340B statute, which is silent as to contract pharmacies' role in the Program. In reaching their decisions, each district court analyzed the statutory text, legislative history, and HRSA's guidance, but the courts arrived at different legal conclusions. Two of the courts ruled that HHS acted within its statutory authority in issuing the violation letters, while two others disagreed. Three of the cases were appealed to the Courts of Appeals for the Third, Seventh, and D.C. Circuits.

Differing outcomes in these cases could lead to more uncertainty around the 340B Program, and could prompt more drug manufacturers to consider whether to restrict covered entities that use contract pharmacies from 340B pricing. (For more information about the contract pharmacy litigation, see CRS Legal Sidebar LSB10842, *Courts Evaluate the Role of Contract Pharmacies in the 340B Drug Discount Program*, by Hannah-Alise Rogers.)

Considerations for Congress

Several questions have arisen around the appropriate interpretation of the 340B statute as well as the scope of HRSA's authority to police general Program compliance. Stakeholders debate whether covered entities should be permitted to use contract pharmacies to dispense 340B drugs and, if so, how many contract pharmacies each covered entity may use. Congress could amend the 340B statute to clarify the role contract pharmacies should play in the 340B Program.

Stakeholders also debate the extent to which the Program helps underserved patients and whether the revenue generated by hospitals from 340B drugs should be passed on to patients or otherwise be used to care for underserved populations. Congress could amend the statute to clarify how covered entities may use the profits attributable to 340B drugs. Congress could also require DSHs seeking to become covered entities to more clearly demonstrate their eligibility for 340B pricing, including by detailing the scope of care the hospitals provide to underserved patients who are ineligible for Medicare or Medicaid.

Congress could also amend the 340B statute to increase HRSA's authority to regulate the Program and its participants. In its FY2023 Budget Justification, HRSA proposed a statutory amendment to provide the agency with rulemaking authority in order to strengthen its oversight of the Program. The agency stated that such authority "would allow HHS to set clear, enforceable standards for participation in all aspects of the 340B Program."

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