Members Brief

An informational brief prepared by the LSC staff for members and staff of the Ohio General Assembly

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Federal 340B Drug Pricing Program

The federal 340B Drug Pricing Program provides access to reduced-price drugs for eligible health care providers registered with the U.S. Department of Health and Human Services as "covered entities." These covered entities include facilities that serve vulnerable communities.

Under the program, 340B covered entities may purchase select outpatient and over-the-counter drugs at discounted prices. These prices are at least as low as the price state Medicaid agencies pay for the same drugs and are often lower. To receive 340B discounted drugs, an individual must be a patient of a 340B entity. In recent years, the number of 340B covered entities has increased dramatically.

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History

The 340B Drug Pricing Program requires drug manufacturers that participate in the Medicaid program to sell outpatient drugs at a discount to certain types of hospitals and other health care providers (referred to as "covered entities"). The program was enacted as part of the "Veterans Health Care Act of 1992"[1] and is named after the section of the Public Health Service

[1] Public Law 102-585.

Act that authorizes it. The 340B program is administered by the Office of Pharmacy Affairs of the Health Resources and Services Administration (HRSA), a division of the U.S. Department of Health and Human Services (HHS). Its purpose is to provide financial relief to facilities that care for the medically underserved.[2] In 2020, sales of drugs under the 340B program were estimated to be approximately 7% of the total U.S. drug market.

340B covered entities

Only covered entities are authorized to participate in the 340B Drug Pricing Program. Several types of hospitals, as well as certain clinics that receive federal grants from HHS, are eligible, as listed below. To participate, a provider must register with HRSA, be approved by it, and follow program requirements.[3]

Types of 340B covered entities[4]
Federally qualified health centers (FQHCs) (including FQHC look-alikes)
Title X family planning clinics
Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics and programs
State-operated AIDS Drug Assistance Programs (ADAP)
Black lung clinics
Hemophilia treatment centers
Native Hawaiian health centers
Urban Indian clinics
State or local sexually transmitted disease clinics and hemophilia treatment centers
Certain disproportionate share hospitals, critical access hospitals, children's and cancer hospitals, sole community hospitals, and rural referral centers[5]

[2] 42 United States Code (U.S.C.) 256b.

[3] Health Resources and Services Administration (HRSA), *340B eligibility*, which may be accessed by searching "340B Drug Pricing Program" on the HRSA website: HRSA.gov.

[4] 42 U.S.C. 256b(a)(4).

[5] A "disproportionate share hospital" is a hospital with a disproportionately large share of low-income patients. Their Medicare and Medicaid payments are adjusted to account for their larger number of low-income patients. (HRSA, *340B Glossary*, which may be accessed by searching "340B glossary" on the HRSA website: HRSA.gov.)

Patients

Any patient of a 340B covered entity may receive covered outpatient drugs through the covered entity. The statute does not define who is a patient, but HRSA guidance states three criteria that an individual must meet to be considered a patient:

1. The 340B covered entity must have a relationship with the individual, evidenced by maintaining the patient's medical records.
2. The individual must receive health care services from a health care provider either employed, contracted, or referred by the 340B entity, and responsibility for the individual's care must remain with the 340B entity.
3. The individual must receive a health care service from the 340B entity that is consistent with the entity's grant funding or FQHC look-alike status. (Disproportionate share hospitals are exempt from this requirement.)[6]

Covered drugs

The 340B program applies to covered outpatient drugs, which are prescription drugs and biologics, other than vaccines, approved by the U.S. Food and Drug Administration and provided in outpatient settings. Covered outpatient drugs include over-the-counter drugs if prescribed by a physician and covered by the state Medicaid program. It does not apply to inpatient drugs and drugs that are bundled with other services for payment purposes.[7]

Pricing

Drug prices through the 340B program are significantly lower than retail and wholesale prices. According to the U.S. Government Accountability Office (GAO), HRSA estimates that 340B covered entities saved an estimated 20%-50% off drug costs, totaling billions of dollars of savings each year.[8]

340B ceiling price

The maximum price that a drug manufacturer can charge a 340B entity for a covered drug is the "340B ceiling price." The 340B ceiling price is calculated as a deduction from the manufacturer's sales price – it is not paid to the covered entity as a separate rebate amount. It is the difference between the drug's average manufacturer price (AMP)[9] and its unit rebate amount

[6] HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Eligibility, final notice,* 61 Fed. Reg. 207 (October 24, 1996).

[7] 42 U.S.C. 1396r-8(k)(2).

[8] U.S. Government Accountability Office testimony statement of Debra A. Draper, Director, Health Care, *Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight (PDF)*, March 24, 2015, which may be accessed by searching that title on the GAO website: GAO.gov.

[9] A drug's AMP is the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. AMP is used to calculate Medicaid rebates and is not publicly available. The Congressional Budget Office has estimated AMP to be about 20% less than the "average wholesale price" (AWP) for drugs. (Robert P. Navarro, *Managed Care Pharmacy Practice*, pg. 379 (2009).)

(URA). A drug's URA is calculated using a statutory formula based on the formula below used to calculate Medicaid drug rebates.[10]

Medicaid unit rebate amounts[11]	
Brand-name drugs	23.1% of AMP (or AMP minus "best price," if greater)
Certain pediatric and clotting drugs	17.1% of AMP (or AMP minus "best price," if greater)
Generic and over-the-counter drugs	13% of AMP

Certain elements of the calculation, such as AMP, are confidential under the 340B program and Medicaid drug discount statutes.[12] Beginning in 2019, HRSA launched a secure website for 340B covered entities that lists the 340B ceiling price for 340B drugs, but because of this confidentiality the information is not publicly available.[13]

Sub-ceiling prices and the 340B Prime Vendor Program

Covered entities may negotiate discounts that are lower than the 340B ceiling prices for drugs, referred to as "sub-ceiling prices." They also may join the 340B Prime Vendor Program, which is a program mandated by the 340B statute.[14] A "prime vendor" is typically a single, preferred wholesaler that specializes in serving a group of customers – in this case, 340B covered entities. Currently, it is managed by a private company, Apexus, through a contract awarded by HRSA.[15] Apexus is responsible for negotiating pharmaceutical pricing below the 340B price and for improving access to affordable medications by establishing a drug distribution network for 340B covered entities. Those entities do not incur any costs or risks in joining the Prime Vendor Program – it is funded through nominal fees charged to distributors and suppliers. These negotiated discounts affect the prices that covered entities pay manufacturers, but do not directly affect the prices paid by consumers. According to Apexus, covered entities that

[10] 42 U.S.C. 256b(a)(1) and (2).

[11] 340B Health, *340B Drug Pricing Program Overview*, which may be accessed on the 340B Health website: 340BHealth.org.

[12] See page 4 of U.S. Department of Health and Human Services Office of Inspector General, July 2006, *Review of 340B Prices (PDF)*, which may be accessed by searching "Review of 340B Prices" on the Inspector General's website: oig.hhs.gov.

[13] Bryan P. Murray, Jennifer Orr Mitchell, The National Law Review, *340B Drug Ceiling Prices Now Available*, Volume XII, Number 13, January 13, 2022.

[14] 42 U.S.C. 256b(a)(8) and (10).

[15] Apexus, *What is the 340B Prime Vendor Program?*, which may be accessed on the Apexus website: Apexus.com.

participate in the Prime Vendor Program realize an average savings of 10%-34% below the 340B ceiling price, as well as lower prices for non-340B items, such as vaccines and medical supplies.[16]

Duplicate discount prohibition

Under federal law, 340B covered entities are prohibited from requesting both a discounted 340B price and a Medicaid drug rebate for the same drug (duplicate discounts).[17] To avoid duplicate discounts, a 340B covered entity must choose whether to "carve in" or "carve out" Medicaid patients. Carving in means using the Medicaid price for 340B program drugs by billing the state Medicaid program for 340B program drugs dispensed to Medicaid enrollees. Carving out means using the 340B price for 340B program drugs by not billing Medicaid for any 340B drugs dispensed to Medicaid enrollees and instead independently billing for those drugs using 340B prices.[18]

Covered entities must notify HRSA of their choice to carve in Medicaid patients, and HRSA maintains a file of covered entities that carve in to help avoid duplicate discounts by state Medicaid agencies. Approximately 65% of covered entities that are hospitals and 37% that are nonhospitals carved in Medicaid patients (in other words, paid the Medicaid rate for 340B drugs dispensed to those patients).[19]

Medicare drug reimbursement rates

In a 2022 decision, the U.S. Supreme Court struck down an HHS rule that established a lower Medicare drug reimbursement rate for hospitals that are 340B covered entities than for hospitals that are not.[20] HHS did not conduct a hospital survey of drug acquisition costs before determining the payment rates. The Court's ruling was based on the federal statute governing Medicare, which permits HHS to vary the drug reimbursement rate among hospital categories if it first conducts a drug cost survey of hospitals.[21] Because HHS did not do so, the Court concluded that the reimbursement rates were unlawful and that HHS could not establish lower drug payment rates for 340B hospitals than non-340B hospitals.

340B program savings

The federal statute does not specify how covered entities must spend their savings and does not require them to document how they use their savings. Practically speaking, there is no guarantee that a covered entity will receive any savings under the 340B program. According to a 2015 study conducted for Congress by the Medicare Payment Advisory Commission, of 29 sampled covered entities, only half reported savings from the program. Of those reporting

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[16] 340B Prime Vendor Program, *340B Prime Vendor Program*, which may be accessed on the 340B Prime Vendor Program website: 340Bpvp.com.

[17] 42 U.S.C. 256b(a)(5).

[18] HRSA, *Duplicate Discount Prohibition*, which may be accessed by searching "duplicate discount prohibition" on the HRSA website: HRSA.gov.

[19] MedPAC, Report to Congress, *Overview of the 340B Drug Pricing Program*, pg. 9, May 2015.

[20] *American Hospital Association v. Becerra*, 596 U.S. ____, 142 S.Ct. 1896, 213 L.Ed.2d 251 (2022).

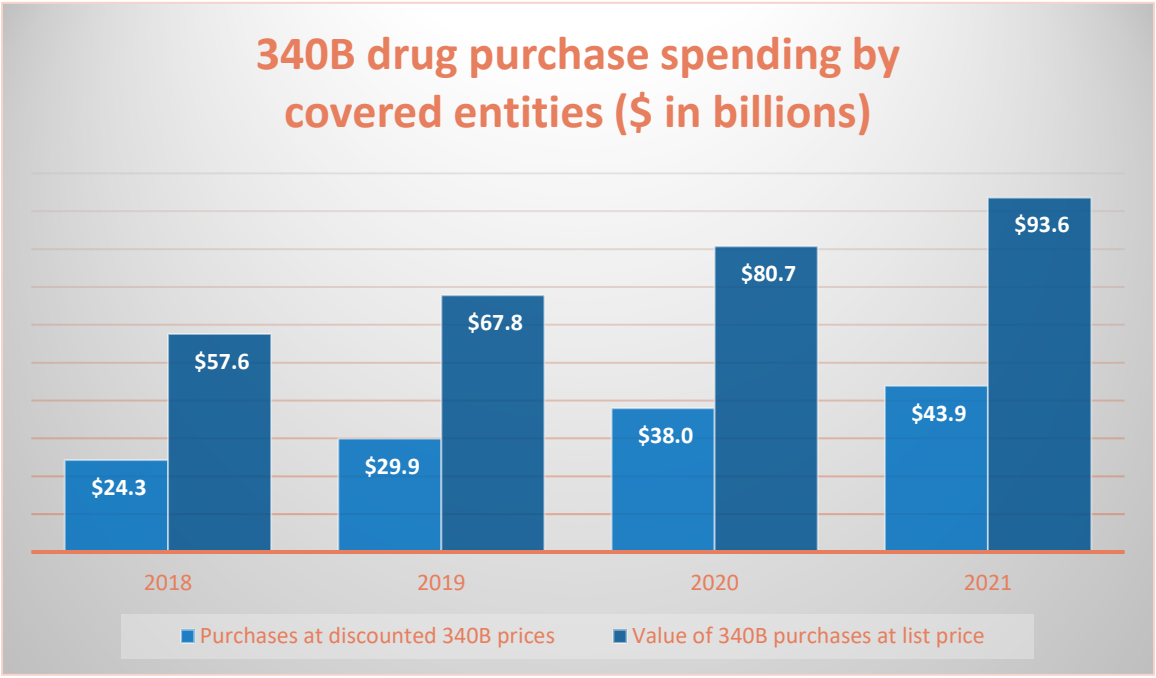
[21] 42 U.S.C. 1395l(t)(14).

savings, most used the increased revenue from those savings to provide additional services and serve more patients.[22]

Recently, pharmacy benefit managers under contract with 340B covered entities have begun to include contract terms requiring the covered entity to give the pharmacy benefit manager all or part of its 340B program savings. In late 2020, the 133rd General Assembly enacted S.B. 263, which prohibits health insurers, Medicaid managed care organizations, pharmacy benefit managers, and other third-party payers from including contract terms that would result in a 340B not receiving full financial relief under the 340B program.[23]

Growth in the 340B program

The 340B program has grown exponentially in recent years, both in the number of covered entities and the amount of drug purchases. According to HRSA data, drug purchases under the 340B program grew from approximately $9 billion in 2014 to approximately $43.9 billion in 2021. Between 2020 and 2021 alone, drug spending under the program increased by more than 15%.[24]



In 2010, the Patient Protection and Affordable Care Act expanded eligibility for the 340B program to cover additional types of facilities, such as critical access hospitals and rural health

[22] MedPAC, *Overview of the 340B Drug Pricing Program*, pg. 8.

[23] S.B. 263, effective April 12, 2021, which is available on the General Assembly's website: legislature.ohio.gov.

[24] Dr. Adam J. Fein, Drug Channels, *The 340B Program Climbed to $44 Billion in 2021*, August 15, 2022, which may be accessed by searching that article name on the Drug Channels website: drugchannels.net.

centers.[25] That same year, HRSA changed its 340B program guidance to permit covered entities to contract with multiple pharmacies instead of just one. Between 2010 and 2020, the number of covered entities, and the number of provider locations affiliated with them, grew dramatically. For example, during the period from 2010 through 2020, data indicates a growth in the number of unique covered entity sites of 23% and a growth in the number of contract pharmacies of 32%.[26] Other factors contributing to the program's growth include Medicaid expansion, increased volume of outpatient care, and increased use of specialty drugs.

[25] Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs (PDF)*, February 2021, pg. 11, which may be accessed by searching that title on the CBO website: CBO.gov.

[26] Shiraz Hasan and Sofi Peterson, IQVIA, *340B Drug Discount Program Growth Drivers*, April 16, 2021, which may be accessed by searching "340B Drug Discount Program Growth Drivers" on the IQVIA website: iquiva.com.