Securing Our Safety-Net: The 340B Drug Pricing Program

The AAMC is committed to advancing policies that help enable our member institutions care for their communities. For over thirty years, the 340B Drug Pricing Program has allowed safety-net hospitals, many of which are teaching hospitals, to stretch their limited financial resources and provide comprehensive health care services to low-income patients, all at **no cost to the taxpayer**. To learn more about the program, watch our "340B Simplified" video, available here.

What is 340B?

340B was first established in 1992 under Section 340B of the Public Health Service Act (PHSA). The program allows certain types of "covered entities" to purchase outpatient drugs at a discount from manufacturers, thereby helping them to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." These covered entities leverage the savings generated by the program to care for under-resourced patients and communities by financing uncompensated care, providing free or discounted medications, and investing in community health programs (such as the creation of affordable housing or mobile health care units).

What types of organizations qualify for covered entity status?

Certain types of federal grantees and qualifying hospitals can participate in the 340B program. These hospitals include: children's hospitals, critical access hospitals (CAHs), disproportionate share hospitals (DSHs), free standing cancer hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs).²

These covered entities share a common mission: to care for under-resourced patients, including low-income Medicare and Medicaid beneficiaries and the uninsured. Their commitment to serving these patients, regardless of their ability to pay, results in narrow or negative financial margins. However, the savings generated by 340B help to offset the difference, ensuring that these vital safety-net organizations can continue to serve their communities.

How does the program work?

Section 340B of the PHSA requires that pharmaceutical manufacturers provide discounts to covered entities in exchange for having their drugs covered under Medicaid and Medicare Part B. The 340B "ceiling price," or the maximum amount that a manufacturer may charge covered entities for a drug, is calculated as the average manufacturer price (AMP) minus the unit rebate amount (URA). This methodology results in average savings between 25 and 50 percent on pharmaceutical purchases, which covered entities use to help serve patients and communities.

How do AAMC member institutions use their 340B savings?

AAMC member institutions reinvest their 340B savings to provide health care services to their patients, as well as finance vital programs. Across the country, academic medical centers use their 340B savings to:

- **Increase access to life-saving medicines** through free or discounted prescriptions, bedside medication delivery, and medication management services.
 - The University of Utah Health leverages their 340B savings to provide free medications to eligible patients through their Medication Support Services (MSS) program. In addition, 340B helps to reduce hospital readmissions through their transitions of care program, in which pharmacists work with high-risk patients access their medications upon discharge.³
- Expand access to specialty care, including behavioral health, oncology, neurology and pneumology.
 - In response to a mounting crisis in children's mental health and a shortage of providers, St. Louis Children's Hospital leveraged their 340B savings to open a new pediatric behavioral health unit.⁴
 - The University of California, San Francisco Health uses 340B to provide costly chemotherapy and immunotherapy services to uninsured and underinsured patients.⁵
- Address the social determinants of health by investing in affordable housing, creating medical-legal partnerships, and implementing community health programs.
 - Virginia Commonwealth University Medical Center uses their 340B savings to ensure that medically complex patients have access to permanent supportive housing. In addition, 340B supports their medical-legal partnership (MLP), which provides patients with free advice and representation on legal issues spanning housing, employment, and public benefits.⁶
- Advance health equity by helping historically marginalized populations access life-saving health care.
 - At the University of California, Los Angeles Health, 340B supports a local partnership to provide medical and behavioral health services to veterans and their families, as well as address the problem of chronic homelessness among veterans.⁷

 Johns Hopkins Medicine leverages 340B to support specialized, population-specific clinics, including the region's only Sickle Cell Center, which provides comprehensive services for a predominantly Black patient population.⁸

340B has a big impact. To learn more about how our members use their savings to benefit patients and communities, we encourage you to refer to our AAMCNews collection on 340B, available here.

Why do we need to protect 340B?

- 340B helps safety-net providers care for low-income, rural, and under-resourced patients and communities. Without the support of this program, many patients could lose access to crucial health care and social services.
- 340B supports access to lifesavings health care services at <u>zero cost</u> to the taxpayer—the savings come from drug manufacturer discounts. In 2019, 340B hospitals provided \$67.9 billion in total benefits to the communities they serve.⁹
- Restricting the scope of 340B would not result in additional funds for the federal government and could potentially leave patients without access to essential health care programs.
- Some pharmaceutical companies have taken steps to severely restrict covered entities' use of the program.
 Beginning in July 2020, a growing number of drug companies have attempted to impose limits on 340B discounts dispensed through arrangements with community-based pharmacies. As of March 2022, the median annualized impact of these restrictions on disproportionate share hospitals, rural referral centers, and sole community hospitals was \$2.2 million, with 10% of these hospitals anticipating annualized losses of \$21 million or more.¹⁰

How is the AAMC working to defend 340B?

The AAMC supports legislation to preserve and strengthen 340B, so that America's safety-net hospitals can continue to care for vulnerable and low-income patients and communities. In addition, we continue to defend this program in the courts.

Challenging Pharmaceutical Companies' Unlawful Restrictions on Community Pharmacy Arrangements

• In 2020, certain drug companies began to try to limit covered entities use of community-based pharmacies to purchase and distribute 340B discounted drugs. The Health Resources and Services Administration (HRSA) issued violation letters to manufacturers that have withheld discounts on drugs purchased by contract pharmacies, informing them that they are in violation of 340B statute and may be subject to civil monetary penalties. In response, several manufacturers filed a lawsuit against the U.S. Department of Health and Human Services to prevent this order from taking effect. The AAMC has filed amicus briefs in support of the government's position that drug companies cannot unilaterally decide not to provide drugs to community pharmacies.

Protecting 340B Access During the COVID-19 Pandemic

• In 2020, the AAMC <u>supported legislative efforts</u> to protect 340B hospitals eligibility for the program during the COVID-19 public health emergency. These protections were ultimately included in the Consolidated Appropriations Act, 2022 (<u>H.R. 2471</u>), which allows 340B hospitals to maintain their eligibility for the program despite changes in their patient mix.

For questions or more information, please contact Sinead Hunt, Legislative Analyst, AAMC Office of Government Relations, at <u>sihunt@aamc.org</u>

¹ 102nd Congress, Second Session. (1992). H.R. No. 102-384, Part II.

² Health Resources and Services Administration. 340B Eligibility. https://www.hrsa.gov/opa/eligibility-and-registration. Accessed Nov. 4, 2022.

³ The University of Utah Health. 340B PROGRAM. https://healthcare.utah.edu/about/340b-program.php#howthe340bprogrambenefitsourcommunity. Accessed Nov. 4, 2022.

⁴ 340B Health. 340B Hospitals in Pursuit of Health Equity: BEST PRACTICES FROM THE FIELD. Washington, DC: 340B Health; 2022. https://www.340bhealth.org/files/Health Equity Report 2021 FINAL.pdf

⁵ University of California, San Francisco (UCSF) Health. Our 340B Story. https://www.ucsfhealth.org/about/our-340b-story. Accessed Nov. 4, 2022.

⁶ Virginia Commonwealth University Health. 340B Drug Pricing Program. https://www.vcuhealth.org/locations/vcu-medical-center/patient-guide/pharmacy-services/340b-drug-pricing-program. Accessed Nov. 4, 2022.

⁷ University of California, Los Angeles (UCLA) Health. 340B Community Health Program. https://www.uclahealth.org/why-choose-us/about/community-health/340b-program. Accessed Nov. 4, 2022.

⁸ Johns Hopkins Medicine. 340B at Johns Hopkins Hospital. <a href="https://www.hopkinsmedicine.org/about/community_health/johns-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopkins-hopk

⁹ American Hospital Association. *340B Hospital Community Benefit Analysis*. Washington, DC: AHA; 2022. https://www.aha.org/system/files/media/file/2022/06/340b-community-benefits-analysis-6-3-22.pdf

¹⁰ 340B Health. CONTRACT PHARMACY RESTRICTIONS REPRESENT GROWING THREAT TO 340B HOSPITALS AND PATIENTS: SURVEY RESULTS. Washington, DC: 340B Health; 2022. https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf