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Fact Sheet: The 340B Drug Pricing Program

The Issue

For more than 30 years, the 340B Drug Pricing Program has provided financial help to hospitals serving vulnerable communities to manage rising prescription drug costs.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include federal grantee organizations and several types of hospitals, including critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations.

The program allows 340B hospitals to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve. Hospitals use 340B savings to provide, for example, free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management and community health programs.

According to the Health Resources and Services Administration (HRSA), which is responsible for administering the 340B program, enrolled hospitals and other covered entities can achieve average savings of 25% to 50% in pharmaceutical purchases. Despite significant oversight from HRSA and the program's proven record of decreasing government spending and expanding access to patient care, some want to scale it back or drastically reduce the benefits that eligible hospitals and their patients receive from the program.

AHA Position

- Protect the 340B program for all providers and ensure the program continues to help providers stretch limited resources and provide more comprehensive services to more patients.
- Advocate that the Department of Health and Human Services (HHS) remedy all affected hospitals for the unlawful Medicare payment cuts and expand drug manufacturer transparency.
- Thwart drug manufacturers' efforts to unilaterally and unlawfully change the 340B program.

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- Support eliminating the orphan drug exclusion for certain 340B hospitals.
- Oppose efforts to scale back, significantly reduce the benefits of, or expand the regulatory burden of the 340B program, including proposals to dramatically expand reporting requirements on certain 340B hospitals and impose a moratorium on new entrants into the program.
- Support expanding the program to reach additional vulnerable communities, including investor-owned hospitals that provide care for underserved populations.
- Support program integrity efforts that are equitable and accountable for both providers and drug companies to ensure adherence to the program's rules and regulations.

Why?

- **340B-eligible hospitals are the safety net for their communities.** The 340B program allows eligible hospitals to further stretch their limited resources and provide additional benefits and services. These hospitals care for a significant share of the nation's underserved populations including children, cancer, and rural patients.
- **The 340B program generates valuable savings for eligible hospitals to invest in programs that enhance patient services and access to care.** Communities in need could lose access to valuable, life-saving care without the financial support from the 340B program.
- **The 340B program is a small program with big benefits.** In 2010, Congress expanded the benefits of the 340B program to CAHs, RRCs, SCHs and free-standing cancer hospitals. While these newly-eligible hospitals represent 54% of actively participating 340B hospitals, the drugs used by these hospitals account for only a small fraction of drugs sold through the 340B program. Other factors that attribute to the program's growth include the increased volume of outpatient care and the increased use of specialty drugs.
- **The Medicare payment cuts to 340B hospitals are unlawful, payment should be restored and other hospital payments should be protected.** As part of the outpatient prospective payment system final rule for calendar year 2018 and subsequent years, CMS implemented drastic cuts to Medicare payments for drugs that are acquired under the 340B program. These payment cuts came on top of the fact that Medicare chronically underpays hospitals for services. The AHA, joined by member hospitals and health systems and other national hospital organizations sued the government over the payment cuts. A federal district court sided with the AHA and found that the payment reductions were unlawful. In June 2022, the Supreme Court unanimously ruled in favor of the AHA. The issue is currently pending before CMS to determine a remedy for these five years of underpayments. Any remedy by CMS must promptly repay 340B hospitals the full amount of money that was unlawfully withheld

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and ensure that all hospitals are held harmless from any recoupments due to the agency's own mistakes.

- **Drug manufacturers are undermining the program.** Several of the largest drug manufacturers have unilaterally stopped providing discounts to 340B drugs dispensed through community and specialty pharmacies that contracted with 340B covered entities, violating the 340B statute. This illegal action threatens the integrity of the 340B program and the savings on which covered entities rely to provide care to millions of low-income Americans. This move is especially outrageous considering hospitals are facing record-high inflationary cost pressures driving negative operating margins for many hospitals around the country.
- **The 340B Program is not a rebate program.** In yet another attempt to damage the program, drug manufacturers are attempting to convert the means by which covered entities access discounted 340B pricing from an upfront discount to a back-end rebate. This approach complicates providers' access to discounts, requires that financially-strapped organizations provide upfront financing and await reimbursement, and adds considerable burden and cost to the health care system. This new rebate model also violates federal policy. AHA has urged HRSA to order drug manufacturers and their third party vendor to immediately halt their attempts to convert the 340B program to a back-end rebate program.
- **The 340B program requires participating hospitals to meet numerous program integrity requirements.** Hospitals must recertify annually their eligibility to participate and attest to meeting all the program requirements; participate in audits conducted by HRSA and drug manufacturers; and maintain auditable records and inventories of all 340B and non-340B prescription drugs. The AHA and its 340B hospital members support efforts that help covered entities comply with the program requirements.
- **340B hospitals are committed to improving transparency.** The AHA is working with its 340B member hospitals on efforts to strengthen the 340B program by increasing transparency in the program and helping 340B hospitals communicate publicly the immense value the program brings to patients and communities, such as through the AHA Good Stewardship Principles.
- **Additional transparency is needed from drug manufacturers.** As a result of AHA's successful lawsuit, HRSA issued its final rule to strengthen the agency's oversight of 340B ceiling prices to discourage manufacturers from raising prices faster than inflation and improve transparency. The AHA is pleased HRSA has implemented this important rule and provided the required web-based information so 340B hospitals can access the 340B ceiling prices. While this is an important first step, additional transparency is needed from drug companies as they continue to raise the prices of their drugs significantly and introduce new drugs at record-high prices.

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