American Hospital Association™
Advancing Health in America

Fact Sheet: The 340B Drug Pricing Program

The Issue

For more than 25 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 community health centers, children's hospitals, hemophilia treatment centers, 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 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 percent in pharmaceutical purchases. Despite increased 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 significantly reduce the benefits that eligible hospitals and their patients receive from the program.

AHA Position

- Supports efforts to rescind the Centers for Medicare & Medicaid Services' (CMS) drastic payment cuts for many hospitals in the 340B program and expand drug manufacturer transparency.
- Supports eliminating the orphan drug exclusion for certain 340B hospitals.
- Opposes 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. These proposals would involve major changes in hospital inventory practices, could prove to be unworkable in mixed-use settings and are unwarranted given the value the 340B program provides to the communities these hospitals serve.
- Believes the 340B program is essential to helping providers stretch limited resources to better serve their vulnerable communities.
- Supports program integrity efforts to ensure this vital program remains available to safety-net providers.

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Why?

- **Many 340B-eligible hospitals are the safety net for their communities.** The 340B program allows these hospitals to further stretch their limited resources and provide additional benefits and services.

- **The 340B program generates valuable savings for eligible hospitals to reinvest in programs that enhance patient services and access to care.**

Key Facts

- **The 340B program is a small program with big benefits.** HRSA estimates the value of the 340B program at 3.6 percent of the total U.S. drug market. However, that figure examines what 340B entities paid for drugs, not the size of 340B discounts. When examining the discounts, the figure drops to less than 2 percent of overall manufacturer revenue. Some stakeholders claim that growth in the 340B program is out of control. 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 53 percent of 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.

- **Court says CMS cuts are unlawful.** As part of the outpatient prospective payment system final rule for calendar year 2018, CMS implemented a drastic cut to Medicare payments for drugs that are acquired under the 340B program. The AHA, joined by the Association of American Medical Colleges, America's Essential Hospitals, and three hospital plaintiffs sued the government over the payment cuts. Late last year, a federal judge ruled in favor of the AHA, saying that the Department of Health and Human Services' "adjustment" by nearly 30 percent of 2018 Medicare payment rates for many hospitals in the 340B program was unlawful. The judge granted AHA's motion for a permanent injunction and ordered supplemental briefing on the question of proper remedy.

- **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.

- **Additional transparency is needed from drug manufacturers.** The AHA is pleased that HRSA, prompted by a lawsuit filed by AHA and others, has issued its final rule to strengthen the agency's oversight of 340B ceiling prices, discouraging manufacturers from raising prices faster than inflation and improving transparency. The AHA continues to urge HRSA to implement this important rule and provide the required web-based information so 340B hospitals can access the 340B ceiling prices.