

## 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% 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

- The 340B program is essential to helping providers stretch limited resources to better serve their vulnerable communities.
- HHS must rescind the drastic and unlawful Medicare payment cuts for many hospitals in the 340B program and expand drug manufacturer transparency.
- Drug manufacturers must not be permitted to unilaterally and unlawfully change the 340B program.
- 340B hospitals must have flexibility in meeting the program's eligibility requirements during the COVID-19 pandemic to account for temporary changes in patient mix.
- 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.
- Supports expanding the program to reach additional vulnerable communities, including investor-owned hospitals that provide care for underserved populations.
- Supports voluntary program integrity efforts already underway to ensure this vital program remains available to safety-net providers.

## Why?

- **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 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.

## Why?

- The 340B program is a small program with big benefits.** HRSA estimates the value of the 340B program at 5% of the total U.S. drug market. 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.** 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 cuts came despite the fact that for outpatient services 340B hospitals had total and outpatient Medicare margins of negative 18.5% and negative 16.7%, respectively. 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. However, in July 2020, two members of the three-judge panel of the U.S. Court of Appeals agreed to overturn that ruling, despite a spirited dissent questioning the majority's deference to the government's position. The AHA is currently petitioning the Supreme Court to overturn these unlawful cuts.
  - **Drug manufacturers are undermining the program.** Some drug manufactures have unilaterally stopped providing discounts to 340B drugs in contract pharmacies, 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 currently responding to immense financial and operational challenges posed by the COVID-19 public health emergency.
  - **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.
  - **340B Hospitals need flexibility during the COVID-19 pandemic.** Some 340B hospitals have faced short-term changes in their patient mix as many patients have avoided care during the COVID-19 public health emergency. This change has negatively impacted some 340B hospitals' Medicare DSH adjustment percentage and thereby threatens their 340B eligibility. 340B hospitals should not have their 340B eligibility threatened because of the challenges posed by the pandemic. The AHA is working to address this issue.
  - **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.