American Hospital Association®

Fact Sheet: The 340B Drug Pricing Program

The Issue

For 25 years, the 340B Drug Pricing Program has provided financial help to safety-net hospitals 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 patients and the communities they serve. For example, hospitals use the 340B savings to provide free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management programs and community health programs.

According to the Health Resources and Services Administration (HRSA), the federal agency responsible for administering the 340B program, enrolled hospitals and other covered entities can achieve average savings of 25 to 50 percent in pharmaceutical purchases.

As part of the outpatient prospective payment system proposed rule for calendar year 2018, the Centers for Medicare & Medicaid Services (CMS) proposes to drastically cut Medicare payment for drugs that are acquired under the 340B program. Specifically, CMS proposes to pay separately payable, non-pass-through drugs (other than vaccines) purchased through the 340B program at the average sales price (ASP) minus 22.5 percent, rather than ASP plus 6 percent.

Despite increased oversight from HRSA and the 340B 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 eligible hospitals and their patients receive from the program.

AHA Position

The AHA:

- Opposes CMS's misguided proposal to cut Medicare Part B payments that punitively targets 340B safety-net hospitals serving vulnerable patients, including those in rural areas, rather than addressing the real issue: the skyrocketing cost of pharmaceuticals;
- Opposes efforts to scale back or significantly reduce the benefits of the 340B program;
- Believes the 340B program is essential to helping safety-net providers stretch limited resources to better serve their communities;
- Supports eliminating the orphan drug exclusion for certain 340B hospitals; and
- Supports program integrity efforts to ensure this vital program remains available to safety-net providers.

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.
- **Clear program guidance will help 340B hospitals.** However, program policy changes should occur with stakeholder consultation and allow for reasonable transition periods.

Key Facts

- **The 340B program is a small program with big benefits. It accounts for only 2.8 percent of the $457 billion in annual drug purchases made in the U.S.** 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 57 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.
- **The 340B program generates valuable savings for eligible hospitals to reinvest in programs that enhance patient services and access to care.**
- **The 340B program requires participating hospitals to meet numerous program integrity requirements.** Hospitals must recertify annually their eligibility to participate in the program 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.
- **HRSA again proposed to delay its final rule on the 340B ceiling price and civil monetary penalties.** The AHA urges HRSA to implement the final rule codifying the "penny pricing policy" to strengthen HRSA oversight of 340B ceiling prices and to discourage manufacturers from raising prices faster than inflation.
- **In 2016, HRSA released its yet-to-be finalized rule to implement provisions required by Congress on the binding administrative dispute resolution process for 340B hospitals and clinics that claim they have been overcharged for drugs purchased through the program.** The AHA supports a well designed dispute resolution process to ensure greater transparency.

Closing the Orphan Drug Loophole

The current orphan drug exclusion policy prevents 340B CAHs, SCHs, RRCs and free-standing cancer hospitals from purchasing some medically necessary drugs at the 340B price. The AHA supports H.R. 2889, the Closing Loopholes for Orphan Drugs Act, which would allow 340B hospitals subject to the orphan drug exclusion to purchase orphan drugs through the 340B program when the drugs are used to treat an illness other than the rare conditions for which the orphan drug designation was given.

Limiting the orphan drug exclusion is critical for some of the most vulnerable patients cared for by these safety-net hospitals, because in many cases, these medically necessary drugs are unaffordable without 340B pricing. The current exclusion policy jeopardizes the financial sustainability of those hospitals, while at the same time providing a financial windfall to drug manufacturers.