

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 final rule for calendar year 2018, the Centers for Medicare & Medicaid Services (CMS) implemented a drastic 30 percent cut to Medicare payments for drugs that are acquired under the 340B program. The AHA, joined by the Association of American Medical Colleges and America's Essential Hospitals, as well as Eastern Maine Healthcare Systems in Brewer, ME, Henry Ford Health System in Detroit and Adventist Health System's Park Ridge Health in Hendersonville, NC, has filed a lawsuit to prevent the cuts.

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:

- Supports H.R. 4392, a bill to rescind CMS's misguided policy that cuts Medicare payments for many hospitals in the 340B program.
- Opposes efforts to scale back, significantly reduce the benefits of, or expand the regulatory burden of the 340B program, including H.R. 4710, and S. 2312. Both bills would dramatically expand reporting requirements on certain 340B hospitals and impose a moratorium on new entrants into the program. However, they do nothing to address calls for more transparency from drug manufacturers.
- Believes the 340B program is essential to helping safety-net providers stretch limited resources to better serve their communities.
- Supports H.R. 2889, legislation to eliminate the orphan drug exclusion for certain 340B hospitals.
- 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.** The AHA is willing to discuss additional transparency on top of the existing yearly recertification process and random audits required of 340B hospitals. However, transparency requirements should not place an excessive burden on already over-regulated hospitals, should not result in harm to any 340B hospitals or the communities they serve, and should correlate with additional transparency from drug manufacturers.

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 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.

Safeguarding the 340B Program

Discussion on Capitol Hill continues to intensify around the 340B program. Many of the proposals under consideration would prove extremely burdensome to 340B hospitals, involve major changes in hospital inventory practices and could prove to be unworkable in mixed-use settings. Placing such onerous hardships on hospitals that provide care to vulnerable populations seems unwarranted given the value the 340B program provides to the communities these hospitals serve.

We also oppose efforts underway to place a moratorium on new 340B hospitals and child sites that meet the eligibility requirements established by Congress from participating in the program. Preventing newly-eligible hospitals from benefitting from the program will prove more costly to the government as 340B savings allow covered entities to focus on preventive medicine, population health and care throughout the lifespan. These efforts help avoid other, more expensive medical interventions, the cost of which would be borne in large part by federal and state government funds if not for the 340B program.