FACTSHEET

The 340B Drug Pricing Program

THE ISSUE

For nearly 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 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. 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.

HRSA, in the fall of 2015, released its long-awaited proposed omnibus guidance covering key areas such patient definition, covered outpatient drugs and hospital eligibility. The final guidance is not expected until late 2016. In addition, on Aug. 11, HRSA released its proposed rule to implement Affordable Care Act provision requiring a binding administrative dispute resolution process for 340B program hospitals and clinics that claim they have been overcharged for drugs purchased through the program.

Despite more oversight from HRSA and the program's proven record of decreasing government spending and expanding patient access to care, some policymakers want to scale it back or significantly reduce the benefits eligible hospitals and their patients receive from the program.

AHA POSITION

The AHA:

- **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 program integrity efforts to ensure this vital program remains available to safety-net providers and encourages HRSA to develop a process to help financially-distressed providers meet new program integrity provisions.**
- **supports extending 340B discounts to the purchases of drugs used during inpatient hospital stays, expanding the program to certain rural hospitals and eliminating the orphan drug exclusion for certain 340B hospitals.**

Continued

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.
- **Better program oversight and clear program guidance will help 340B hospitals.** However, program policy changes should occur with stakeholder consultation and allow for reasonable transition periods.
- **Expanding the program to the inpatient setting would be a "win-win" for taxpayers and hospitals.** This expansion would generate savings for the Medicaid program by requiring hospitals to share with Medicaid a percentage of their savings on inpatient drugs administered to Medicaid patients. It also would reduce Medicare costs, as CAHs are paid 101 percent of their inpatient and outpatient costs by Medicare, and the 340B pricing mechanism would lower CAHs' drug costs.

KEY FACTS

- **The 340B program is a small program with big benefits. It accounts for only 2 percent of the $374 billion in annual drug purchases made in the U.S.** Some stakeholders claim that growth in the 340B program is out of control. Congress through the Affordable Care Act expanded the benefits of the 340B program to CAHs, RRCs, SCHs and free- standing cancer hospitals, but the drugs used by these hospitals account for only a small fraction of drugs sold through the 340B program. Given the increasingly high cost of pharmaceuticals, the 340B program remains essential to creating healthier communities.
- **The 340B program generates valuable savings for eligible hospitals to reinvest in programs that enhance patient services and access to care.** While many hospitals use the 340B savings to provide free or reduced-price prescription drugs to vulnerable patient populations, the savings also allow hospitals to provide more patient services and programs. For example, hospitals use the 340B savings to provide free care for uninsured patients, as well as offer free vaccines, services in mental health clinics, medication management programs and community health programs.
- **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 program integrity efforts that help covered entities comply with the program requirements.

HRSA PROPOSALS FOR 340B PROGRAM

HRSA's proposed omnibus guidance and dispute resolution rule. The AHA is concerned that HRSA's proposed omnibus guidance for the 340B program would jeopardize hospitals' ability to serve vulnerable populations, including low-income and uninsured individuals and patients receiving cancer treatments. The AHA expressed strong concerns about many of the agency's proposals related to defining patient eligibility for the program, and opposes HRSA's proposal to exclude from 340B pricing outpatient drugs that are reimbursed as part of a bundled Medicaid payment. The AHA urged HRSA to revise significantly its proposed guidance to allow hospitals to continue their work advancing the health of individuals and communities, even in the face of the rapidly rising pharmaceutical costs. Among other changes, the AHA urged HRSA to withdraw its proposal so that patients receiving infusion services provided at 340B hospitals or their outpatient sites can continue to qualify for 340B drug discount pricing. With regard to the proposed rule on establishing a dispute resolution process, the AHA believes the proposed rule is a good first step but remains concerned that hospitals do not have access to the 340B drug ceiling price information that HRSA would require them to submit as part of a dispute initiation.