American Hospital Association®

340B Drug Pricing Program

Background

For more than 20 years, the 340B Drug Pricing Program has provided financial relief to certain safety-net hospitals for high 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 uninsured and low-income patients. Eligible health care organizations include community health centers, children's hospitals, hemophilia treatment centers, critical access hospitals (CAHs), sole community hospitals, rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals that serve low-income and indigent populations.

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. Despite recent HRSA efforts to exert more program oversight and the program's proven record of decreasing government spending and expanding patient access to medical services, some in Congress are likely to continue their efforts to significantly reduce the benefits eligible hospitals and their patients receive from the program. HRSA is expected to issue by June 2014 a comprehensive rule that will examine several areas pertinent to the 340B program, such as the definition of patient eligibility, contract pharmacy arrangements, and mechanisms to prevent ineligible patients from receiving the benefit and duplicate discounts for Medicaid patients.

AHA View

While the 340B program accounts for only 2 percent of the $325 billion annual drug purchases in the U.S., it provides enormous benefits to safety-net providers and the patients they serve. In fact, 340B hospitals account for 62 percent of all the uncompensated care provided in U.S. hospitals and benefit from annual drug savings of $1.6 to $3.2 billion per year.

The AHA believes the 340B program is essential to helping safety-net providers stretch limited resources to better serve their communities. The program creates valuable savings on outpatient drug expenditures, allowing providers to reinvest the funding in patient care and health services to benefit the communities they serve. It also saves money for state and federal governments.

The AHA opposes all efforts to scale back or significantly reduce the benefits of the 340B program. Better program oversight and clear program guidance could help 340B hospitals, but policy changes should occur with stakeholder consultation and allow for reasonable transition periods for any significant regulatory change.

The AHA 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. HRSA has implemented several 340B program integrity measures,

including audits and annual recertification for 340B entities. HRSA also issued guidance in 2013 that disproportionate share, children's and free-standing cancer 340B hospitals are prohibited from using group purchasing organizations (GPOs) to purchase any outpatient drugs. However, these hospitals may purchase all inpatient drugs through a GPO. Based on feedback from the AHA and its 340B member hospitals, HRSA extended the implementation deadline allowing additional time for stakeholders to make the necessary changes to comply with the guidance.

The AHA supports eliminating entirely the orphan drug exclusion for certain 340B hospitals that was included in the Affordable Care Act (ACA). However, the AHA supported HRSA's approach in a July 2013 regulation implementing the ACA orphan drug exclusion provision for RRCs, CAHs and free-standing cancer hospitals. The final rule allows RRCs and CAHs to purchase orphan drugs as long as these drugs are not used to treat rare conditions or diseases, which limits the exclusion for these hospitals and provides greater access to 340B discounted drugs. The rule included several AHA-supported modifications, such as allowing hospitals subject to the exclusion to establish an alternative compliance system and permitting free-standing cancer hospitals to opt out of using the 340B program to purchase orphan drugs and instead purchase the orphan drugs through a GPO. The Pharmaceutical Research and Manufacturers of America filed a lawsuit in federal district court to stop HRSA's implementation of the orphan drug final rule. The AHA filed an amicus brief supportive of HRSA's interpretation of the orphan drug exclusion.

The AHA supports extending 340B discounts to the purchases of drugs used during inpatient hospital stays, and expanding the program to certain rural hospitals. Expansion of the program would be a "win-win" for taxpayers, as well as for hospitals. Expanding the 340B program to inpatient drugs can generate significant savings for the Medicaid program by requiring hospitals to rebate Medicaid a percentage of their savings on inpatient drugs administered to Medicaid patients. This change 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. According to the Congressional Budget Office, expanding the program to cover inpatient services would save the federal government more than $1.2 billion over 10 years.