

The 340B Drug Pricing Program

THE ISSUE

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in the Medicaid drug rebate program to sell outpatient drugs at discounted prices to taxpayer-supported health care facilities that care for uninsured and low-income people. The program enables eligible entities, including hospitals and community health centers, to stretch scarce federal resources to reduce the price of pharmaceuticals for patients, expand services offered to patients and provide services to more patients. In addition, the program generates savings for the federal and state governments.

In 1990, Congress established the Medicaid drug rebate program, which requires drug manufacturers to enter into and have in effect a rebate agreement with the Secretary of Health and Human Services (HHS). The rebate agreement requires pharmaceutical manufacturers to supply their products to state Medicaid programs at the manufacturer's "best price" – that is, the lowest price offered to other purchasers. On the heels of the Medicaid

drug rebate law, Congress extended similar savings from high drug costs to safety-net providers through the establishment of the 340B Drug Pricing Program.

Section 340B covered entities 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.

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 340B program oversight and the program's proven record of decreasing government spending and expanding patient access, some in Congress may attempt 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.

The AHA believes the 340B program is essential to helping safety-net providers stretch limited resources to better serve their communities.

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.

The AHA supports extending the 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.

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WHY?

- **Many 340B-eligible hospitals are the safety net for their communities.** The program allows these hospitals to further stretch their limited resources and provide additional benefits and services to their communities.
- **Better program oversight and clear program guidance will help 340B hospitals.** But program policy changes should occur with stakeholder consultation and allow for reasonable transition periods.
- **Expansion of the program would be a “win-win” for taxpayers, as well as for hospitals.** Expanding the 340B program would generate 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 upwards of \$1.2 billion.

KEY FACTS

HRSA has implemented several 340B program integrity measures. These include audits of 340B entities and annual recertification. These measures stem from a 2011 Government Accountability Office (GAO) report that criticized HRSA’s oversight of the program. For example, based on preliminary findings from the hospital 340B audits, in February 2013 HRSA issued a 340B program notice intended to clarify program policy regarding the statutory prohibition against obtaining outpatient drugs through a group purchasing organization (GPO). Disproportionate share, children’s and free-standing cancer 340B hospitals are prohibited from using GPOs to make any outpatient drug purchases, but they may purchase all inpatient drugs through a GPO.

HRSA initially allowed covered entities only 60 days after the publication of the GPO policy notice to make certain their 340B inventory management practices complied with the GPO policy. Based on feedback from the AHA and its 340B member hospitals, HRSA extended the compliance deadline to six months to allow time for stakeholders to make the necessary changes.

HRSA in July 2013 finalized its regulation implementing the orphan drug exclusion for RRCs, CAHs and free-standing cancer hospitals. It allowed these hospitals to purchase orphan drugs, as long as these drugs are not used to treat the rare conditions or diseases for which they received orphan status, which limits the exclusion for these hospitals and provides them greater access to 340B discounted drugs. The AHA supports

HRSA’s limitation on the orphan drug exclusion. In addition, the regulation 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.

In September 2013, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit in federal district court to stop HRSA’s implementation of the orphan drug final rule, basing its challenge on the contention that HRSA lacks the authority to issue regulations. The AHA filed an amicus brief supportive of HRSA’s interpretation of the orphan drug exclusion. On May 23, 2014, the U.S. District Court for the District of Columbia ruled against HHS and HRSA in support of PhRMA’s claim that the agency does not have authority to impose its interpretation through rulemaking. HHS and HRSA subsequently issued their orphan drug policy on July 21 as “interpretive guidance.” On Aug. 27, the court, in its final judgment, stated that PhRMA’s efforts to block the interpretive guidance is outside the scope of this case and that PhRMA would have to file a new lawsuit to challenge the agencies subsequent actions. HRSA also plans to issue a comprehensive proposed regulation, known as the “Mega Rule” to address such issues as eligibility, patient definition and contract pharmacy. In light of the court’s decision, HRSA’s release of the proposed rule may be delayed.

340B HOSPITAL ELIGIBILITY

340B Eligible Hospital	DSH%	GPO Prohibition	Orphan Drug Exclusion
Disproportionate Share Hospital	>11.75%	Yes	No
Children’s Hospital	>11.75%	Yes	No
Cancer Hospital	>11.75%	Yes	No
Critical Access Hospital	N/A	No	Yes
Sole Community Hospital	≥8%	No	Yes
Rural Referral Center	≥8%	No	Yes

*Source Apexus and HRSA, 2013

