HAP
The Hospital + Healthsystem Association of Pennsylvania

340B Drug Pricing Program

In 1992, Congress established the 340B drug pricing program to help health care providers that care for a high number of low-income and uninsured patients stretch scarce federal resources as far as possible. The program requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at a discounted price to select health care organizations These discounts are provided at the expense of drug companies, not taxpayer dollars.

Eligibility—Since its inception, the 340B program has supported critical rural and urban health care providers.

- Eligible entities include Federally Qualified Health Centers, Critical Access Hospitals (CAH), children's hospitals, disproportionate share hospitals, cancer centers, rural referral centers (RRC), and select sole community hospitals (SCH).
- In Pennsylvania, less than 25 percent of the 269 hospitals (67) qualify to participate in the program. This includes 75 percent of the commonwealth's CAHs.
- Covered entities may dispense 340B drugs through in-house pharmacies or contract with outside retail pharmacies to dispense the drugs on their behalf. Many covered entities do not have the capacity to operate in-house pharmacies and rely on this provision to participate.

Program Focus and Use—Congress extended eligibility to additional rural and cancer hospitals in 2010.

- The added classes of hospitals—CAHs, SCHs, RRCs and cancer hospitals—represent 54 percent of participating 340B hospitals. The drugs used by these hospitals account for only a small fraction of drugs sold through the 340B program.
- The benefit of the program has grown in part due to the increased volume of outpatient care and the increased use of specialty drugs.

Requirements and Oversight—340B-eligible entities must meet criteria to participate in the 340B program and are subject to oversight.

- Entities must recertify each year to continue to be eligible for 340B discounts.
- The Health Resources and Services Administration (HRSA) has authority to audit drug manufacturers and covered entities and impose penalties for noncompliance on either side.
- 340B eligible entities have been the primary focus of HRSA audits despite continued reports of drug maker underpayment and restrictive policies to limit or deny 340B pricing. Last year, more than 200 hospitals were audited for compliance with 340B program requirements.

Community Benefit—Many 340B hospitals are the lifelines of their community but are financially vulnerable.

- In Pennsylvania, 30 percent of 340B hospitals operate with a negative margin.
- Enrolled hospitals can achieve average savings of 25 percent to 50 percent in pharmaceutical purchases. 340B hospitals use the savings they receive on the discounted drugs to reinvest in programs that enhance patient services and access to care, as well as provide free or reduced-price prescription drugs.
- The IRS Form 990, Schedule H, which is publicly available, provides information on some ways hospitals are reinvesting 340B savings into community programs.
- In 2020, 340B hospitals provided $84.4B in total benefits to their communities. Total community benefits for 340B hospitals increased from $67.9 billion in 2019 to $84.4 billion in 2020, an over $16 billion or 25 percent increase, even during an unprecedented pandemic.

What Needs to Be Done?—As pharmaceutical costs continue to increase—for both patients and providers, the 340B program remains essential to creating healthier communities.

- Prevent pharmaceutical companies from undermining the 340B program, reducing access and quality of care available for low-income and uninsured individuals.
- Ensure pharmaceutical manufacturers participate in the program. HHS should prevent manufacturer-imposed restrictions limiting access to medicines.

December 2023