The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

July 28, 2023

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Senators Thune, Stabenow, Moore Capito, Baldwin, Moran, and Cardin:

On behalf of 235 member hospitals, health systems, and other health care organizations, The Hospital and Healthsystem Association of Pennsylvania (HAP) is grateful for the opportunity to comment on your request for information regarding the 340B program. In Pennsylvania, 45 percent of our hospitals (in 30 counties) participate in the 340B program and serve our most vulnerable populations. About half are in urban areas, and half are in rural areas. Eighty (80) percent of the state's Critical Access Hospitals (CAH) are part of this program.

Congress created the 340B program to permit safety net hospitals that care for a high number of low-income and uninsured patients "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." 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. The 340B program has been critical in helping hospitals expand access to life-saving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country for more than 30 years. According to a report by the Commonwealth Fund, drugs purchased through the 340B program accounted for only 7 percent of the total U.S. drug market.

Many 340B hospitals are the lifelines of their community, and the discounts they receive through the 340B program enable these organizations to care for patients. However, these facilities are financially vulnerable. One out of every four 340B hospitals had a negative operating margin. In Pennsylvania, 30 percent of the 340B hospitals operate with a negative margin. 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. Some examples of things that Pennsylvania 340B hospitals are doing with the savings include:

- Providing financial assistance to patients unable to afford their prescriptions
- Providing clinical pharmacy services, such as disease management programs or medication therapy management
- Funding other medical services, such as obstetrics, diabetes education, oncology services, and other ambulatory services
- Establishing additional outpatient clinics to improve access
- Create new community outreach programs
- Offering free vaccinations for vulnerable populations

What specific policies should be considered to ensure Health Resources and Services Administration **(HRSA) can oversee the 340B program with adequate resources?**

HAP believes that, under current statute and regulation, HRSA has the needed authority to enforce the rules and requirements of the 340B program. In 2010, the agency's authority grew dramatically with the creation of the Administrative Dispute Resolution (ADR) process specific to this program. Through this process, drug manufacturers and covered entities can dispute Medicaid duplicate discounts, claims of diversion, and overcharges. To date, the process has not been implemented as intended by Congress and has faced several legal challenges.

In addition to the ADR process, HRSA has authority to approve or deny eligibility on an annual basis, audit covered entities and drug manufacturers, and impose civil monetary penalties for noncompliance. However, to date, covered entities have been the primary focus of HRSA audits despite continued reports of underpayment and unlawful and restrictive policies created by drug manufacturers to limit or deny 340B pricing to covered entities. As the American Hospital Association (AHA) reported, last year alone, more than 200 hospitals were audited for compliance with 340B program requirements while only 6 percent of drug manufacturers were audited.

HAP joins the AHA in urging HRSA to finalize the ADR rule and to clearly outline a process by which 340B entities can address wrongful restrictions and underpayments imposed by drug manufacturers. HAP would also ask that Congress mandate HRSA increase the number of audits of drug companies for underpayments and restrictive policies.

What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Under the 340B program, covered entities are permitted to dispense 340B drugs to patients through contract pharmacy arrangements. Covered entities rely on these contract pharmacy arrangements to increase patient access to needed medications—especially in rural areas and to address supply chain issues and shortages.

Since this policy went into place, drug companies have attempted to circumvent program requirements by limiting or denying 340B drug pricing to covered entities with contract pharmacy arrangements. In 2021, HRSA reviewed the policies of six manufacturers who placed "restrictions on 340B pricing to covered entities that dispense medication through pharmacies" and found that the manufacturers overcharged the covered entities in direct violation of 340B statute. Unfortunately, this practice is not uncommon. As noted in the comments submitted by the AHA, since 2020, the actions by more than 20 of the largest drug companies in the country to restrict, condition, or outright deny 340B pricing for drugs dispensed through contract pharmacy arrangements are costing disproportionate share hospitals on average $3 million per year in reduced 340B savings.

HAP joins the AHA in urging Congress to codify protections for contract pharmacy arrangements in the federal 340B statute.

What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

HAP would respectfully call the Senators' attention to the issue of discriminatory pricing by pharmacy benefit managers (PBM). Over the last several years, many PBMs have been using "two-tier" pricing models through which they provide lower reimbursement rates to providers participating in the 340B program than those providers that are not. Covered entities are essentially forced to accept unfair terms and policies in order to participate in pharmacy networks. Some PBMs disallow members from using 340B

pharmacies or even exclude hospital-based pharmacies from their networks outright. This practice directly impacts patient access by steering savings intended for 340B entities and ultimately their communities, to payors and PBMs. It has grown to be so problematic that 16 states have already passed laws addressing PBM discriminatory practices against 340B covered entities, and others are actively exploring similar action.

HAP would ask that Congress prohibit PBMs from implementing policies that provide differential reimbursement to 340B providers, those that steer patients away from 340B pharmacies, and those that require patients to procure medications prior to a needed procedure (commonly referred to as "whitebagging" or "brownbagging").

What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

HAP is supportive of the 340B Protect Act (H.R. 2534) that, among other things, would prohibit discriminatory actions by PBMs, impose civil monetary penalties on PBMs that violate the new protections, and create a national data claims clearinghouse to prevent Medicaid duplicate discounts. The legislation specifically outlines a process by which HHS could contract with a third-party entity to collect and review 340B drug claims that were reimbursed by state Medicaid agencies and ensure the claims are not included in any additional rebate requests. This would provide a uniform solution to an issue that states across the country are currently working on.

What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

Pennsylvania hospitals enrolled in the 340B program deeply value and appreciate their ability to use 340B savings to further extend needed care to vulnerable populations. There are existing hospital reporting requirements associated with this program, for example, reinvestments into the community are already reported in Medicare cost reports (through uncompensated care, charity care, and Medicaid shortfalls) and for our non-profit hospitals on IRS-990 Schedule H worksheets (investments in research, community health, and workforce training programs). Other reinvestments are less linear but remain impactful such as shifting savings to much needed service lines that suffer from chronic underpayment (behavioral health is one example).

In stark contrast, drug companies are not required to report any information about how

they set their prices, how they determine when and how much to increase prices, when they implement restrictive policies, or what criteria, if any, was considered in that decision-making.

HAP strongly urges on Congress to increase oversight of drug manufacturers' pricing practices and overt and unlawful attempts to shrink the 340B program.

Thank you for the opportunity to provide comments on this critical program that is a lifeline for so many of our member hospitals.

Sincerely,

John Myers
Vice President, Federal Advocacy