The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

April 1, 2024

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

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

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

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

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

On behalf of over 230 member hospitals, health systems, and other health care organizations, The Hospital and HealthSystem Association of Pennsylvania (HAP), appreciates the opportunity to provide feedback on the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of (SUSTAIN) 340B Act bipartisan discussion draft and accompanying request for information on the 340B Drug Pricing Program. The 340B program was created with the intention of helping hospitals provide valuable services in low-income and rural communities. The Pennsylvania hospital community is supportive of changes that strengthen the program and appreciates the efforts of this group to protect it.

In Pennsylvania, 65 hospitals rely on the 340B program to ensure that they can provide comprehensive health care services to their patients and communities. In the commonwealth, enrolled rural and urban hospitals face unique challenges navigating this already complex program to meet the needs of the underserved communities they care for. Our hospitals interact with the program in a variety of ways. Some have invested in large-scale pharmacy operations or own specialty pharmacies, and others rely solely on contract pharmacies to help meet their patients' needs. This variability requires careful consideration of unintended consequences that may arise out of efforts to make program improvements to avoid inadvertently harm patients and hospitals and patients on either end of this spectrum.

The program is more important than ever to our members in light of continually rising drug prices and ongoing financial pressures. During 2022, drug prices increased an average of 15 percent, and the median drug price has increased by 35 percent. In Pennsylvania, 39 percent of hospitals have a negative operating margin. Hospitals cannot keep pace with these increases, especially when Medicare and Medicaid rates, which account for 50 percent of payments in Pennsylvania, remain woefully inadequate.

In Pennsylvania, 41 percent of the 340B hospitals operate with a negative margin. 340B hospitals use the savings they receive on 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 how Pennsylvania 340B hospitals use 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.
- Creating new community outreach programs.
- Offering free vaccinations for vulnerable populations.

Contract Pharmacies

In your explanatory statement and Request for Information, you indicate concerns regarding the number of contract pharmacies used by some covered entities. It is important to note that contract pharmacies are a primary source to ensure consistent access to needed medications in most programs. In many cases, patients can't travel to a covered entity to fill a prescription, and even if they could, most hospitals aren't able to stock all the drugs their patients need.

Most covered entities rely on relationships with specialty pharmacies to help treat rare or complex medical conditions, and the specialty drug landscape is particularly challenging to navigate. As noted by the American Hospital Association (AHA), 75 percent of all specialty pharmacy arrangements are with four providers, which creates an extreme imbalance of power in contract negotiations. Our member hospitals report that some specialty pharmacies require covered entities to contract with 10–12 additional pharmacies in the rare event that there may be an issue with distribution of a needed medication. This artificially increases the number of contract pharmacy arrangements in use. In addition, essentially all major pharmacy benefit managers (PBM) operate their own mail-order pharmacies and specialty pharmacies and attempt to steer patients to their own pharmacies.

Drug companies already restrict access to the 340B program by denying discounted pricing for outpatient drugs dispensed through contract pharmacy arrangements. They also arbitrarily designate drugs as "limited distribution" so the only way to access those drugs is through specific stores contracted with the manufacturer. These actions limit drug availability to patients and increase the need for contract pharmacy agreements. Pennsylvania 340B hospitals strongly support prohibiting manufacturers from engaging in discriminatory distribution or pricing policies against 340B entities or their contracted community and specialty pharmacies.

The reliance on contract pharmacy arrangements isn't specific to rural communities but is ubiquitous among most of Pennsylvania's 340B hospitals. Hospitals are best equipped to know

which entities to contract with based on the location and needs of their patients, including which specialty pharmacies carry the drugs their patients need. Any cap on contract pharmacy arrangements would hinder covered entities' ability to access the programs and make it harder for patients to get the medications they need. We echo the AHA's request to ensure hospitals maintain the needed flexibility to contract with pharmacies based on the needs of their patients and communities and that safeguards be put into place that restrict drug companies from imposing distribution restrictions or conditions on access to 340B drugs.

Patient Definition

Any definition of patient considered for incorporation into 340B statute needs to offer a high degree of flexibility to account for the dynamic nature of the health services environment; the range of provider/patient relationships; and the diverse pathways that support care for patients with unique health concerns. Models of care delivery are changing to accommodate a variety of patient care and staffing needs. In a post-COVID era, more patient relationships are being managed via telemedicine than ever before and meaningful patient relationships become harder to define.

The metrics mentioned in the discussion draft will not provide a meaningful framework. It would be incredibly difficult to define clinically significant care. For example, infusion, in and of itself, would be clinically significant. However, the clinical significance of ongoing patient care management is arguably just as meaningful, especially as we shift to population health-based models of care. Timeframes are also difficult to justify. Patients delay care for a variety of reasons that shouldn't impact eligibility for the program. Just last year, almost 40 percent of Americans reported delaying care, a trend that is more prevalent among lower-income adults.

Narrowing the patient definition seems to contradict the very reason for the program to ensure access to care. The AHA makes the argument that the 1996 definition has "stood the test of time" and continues to provide the most flexibility going forward. We support the AHA's advocacy on this front. Further, changing the definition of patient could have unintended effects on highly valued components of this program including the availability of discounts for discharge prescriptions and referral prescriptions.

Child Sites

Patient care has increasingly shifted to outpatient settings during the last several years, resulting in an increased number of child sites. This increase has broadened access to patient care, and the ability to register child sites for the 340B program has allowed covered entities to extend care to areas they might not otherwise be able to operate in due to concerns over financial viability.

Capping the number of child sites a covered entity can register or requiring a child site to offer a meaningful range of services ultimately compromises care for the patients. Many services that

were traditionally inpatient are now provided in outpatient facilities that may not offer a broader range of services but are still deserving of 340B eligibility because of the patient populations they serve. Requiring a "meaningful range of services" is not only ambiguous, but it also does not recognize current pediatric patient care models.

We would like to take this opportunity to bring to light our concerns regarding the current registration process and delays in child site designation. Requiring covered entities to register child sites prior to eligibility for 340B discounts often results in the site operating at a loss for 18–24 months. The financial impact of delays in eligibility makes it difficult to open new child sites in underserved locations due to the financial constraints. The unintended consequence of this policy is a reduction in patient access in the areas most in need of access to care.

The discussion draft also references concerns regarding community reinvestments. The intention of the program was always to provide savings to the covered entities for reinvestment as they saw fit based on the current operating landscape. Hospitals have used these funds to expand facilities and services and implement discharge medication program service support and clinical coordination and drug adherence programs. These reinvestments in the community would not be reflected in reports on uncompensated care or charity care, but undoubtedly benefit the community.

Some additional ways our health systems extend 340B pricing to underserved communities include diabetes management programs where supplies are given for free, as well as access to high-cost medications that aren't otherwise covered such as radioplex to help with burns related to radiation therapy. In rural areas, sometimes savings are reinvested in staffing due to higher salary requirements that have become necessary for retention. Limiting the ability of hospitals to reinvest 340B savings will severely harm hospitals and undermine patient care and access.

The rural hospitals in HAP's membership are deeply concerned regarding orphan drug exclusion policies within the current program framework and ask that you consider exceptions to the policy for sites of care in rural or high-need areas. Free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals are often excluded from procuring these high-cost drugs at 340B pricing. This policy unnecessarily creates significant treatment barriers for patients located in these communities served.

Transparency

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. Many of their 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 in IRS-990 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 suffering from chronic underpayment (behavioral health is one

example). Tracking financial demographics, charity care, and payor mix at each site of care, as outlined in the draft bill, would be incredibly difficult because fully clinically and financially integrated child sites are designed to capture many of these metrics at the system level.

HAP member hospitals encourage you to carefully consider how savings from the 340B program are calculated and to avoid methodology that would misrepresent the savings achieved by participating hospitals. When a hospital purchases a drug outside of the 340B program, it is more often than not purchased at the group purchasing organization price, not the wholesale acquisition cost (WAC) price. Any calculations of savings that use the WAC price artificially inflate the actual value of purchasing the drug through the 340B program.

In 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, or when they implement restrictive policies.

Program Integrity

HAP believes the program integrity measures already in place for covered entities are more than sufficient to protect the 340B program and similar measures should be put into place for drug companies. Hospitals already conduct frequent self-audits to ensure compliance and are subject to HRSA audits under the program's current framework. In the AHA's comments, you will see that 1,720 covered entities were audited since 2012. Less than six audits of drug companies were conducted during the same timeframe.

We have concerns regarding any requirement that oversight be extended to contract pharmacies and what that would mean for patient access in our rural and underserved communities. Subjecting contract pharmacies to audits would limit their desire to participate in the program and hospitals' ability to contract with them. Program integrity is already assured through hospital audits. Furthermore, any requirements to submit written contracts with pharmacies could result in further imbalance in the system for hospitals by exposing their sensitive business information and would seemingly run afoul of anti-trust laws.

Program integrity requirements should extend to drug companies who frequently try to circumvent policies by overcharging or denying 340B pricing or placing drugs in limited distribution.

Duplicate Discounts

340B hospitals in Pennsylvania work in good faith with the state Medicaid program and remain committed to ensuring that duplicate discounts are avoided. While we appreciate the intent behind the proposal to create a national clearinghouse as a mechanism to prevent duplicate discounts, collecting all-payor claims data from all covered entities and child sites would place a significant burden on hospitals. If any of the data collected were to be shared with drug

companies, it could be used to weaken the program and harm patients. Commercial claims data disclosure in particular would negatively impact hospitals and ultimately undermine the 340B program. We echo the concerns of the AHA and 340B Health regarding the statutory amendments and agency oversight of this clearinghouse and ask that the clearinghouse be placed in the 340B Section of the Public Health Services Act and under the authority of CMS so that the data collected could not be used to dismantle the program.

The corresponding section of the draft bill (Section 8) includes requirements for hospital financial assistance policies that would extend "a sliding fee scale for covered outpatient drugs dispensed to patients under the drug discount program." Our member hospitals have expressed concerns regarding the level of difficulty operationalizing this requirement would present and the impact it would have on the savings the program would continue to bring to the covered entity. Hospitals don't know at the point of sale whether a drug is 340B eligible and therefore would not know when to offer the sliding fee scale. This requirement would also seemingly impact contract pharmacies and could deter them from wanting to participate in the program.

Concerns Regarding Pharmacy Benefit Mangers

PBMs reduce the scope and benefits created by the program for patients and providers. This includes creating policies and paying 340B hospitals less than non-340B hospitals; steering patients to in-network pharmacy locations; establishing barriers for contract pharmacies to participate in networks; excluding hospital-based pharmacies from networks entirely; lowering rates to hospitals receiving 340B savings; and holding hospitals hostage to unfair contractual terms to participate in networks. HAP encourages you to support efforts to prohibit PBMs and insurers from discriminatory pricing.

User Fees

HAP continues to oppose any proposal to institute a user fee as part of participation in the 340B program. Any requirement to pay HRSA a fee chips away at the savings the program was created to provide, and limits covered entities' ability to reinvest those savings to the fullest extent possible.

We appreciate this group's efforts to protect the 340B program from insurer and pharmaceutical company practices and other threats that stand to jeopardize patient care.

Thank you,

John Myers
Vice President, Federal Advocacy