WISCONSIN HOSPITAL ASSOCIATION

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April 1, 2024

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 our more than 150 member hospitals and integrated health systems, the Wisconsin Hospital Association (WHA) appreciates the opportunity to provide comments on this bipartisan request for information on the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future (SUSTAIN) 340B Act.

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small Critical Access Hospitals, mid, and large-sized academic medical centers. We have hospitals in every part of the state—from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

The 340B Prescription Drug Discount Program is a hugely beneficial program that helps stretch scarce federal resources to support the delivery of high quality, high value health care in Wisconsin. A little more than half (81) of Wisconsin's 150 hospitals participate in the 340B prescription drug program.

Sense of Congress

WHA appreciates Congress officially recognizing through the Sense of Congress words that capture the spirit of the congressional report language when the statute was originally passed in 1992 that identified the purpose of the 340B prescription drug discount program is to stretch scarce federal resources to provide more comprehensive care to more patients.

Fixing Contact Pharmacy and Pharmacy Benefit Manager Obstruction of 340B

First and foremost, WHA is extremely supportive of language codifying in federal statute the long-standing policy of the Health Resources and Services Administration (HRSA) recognizing the use of community pharmacies that contract with 340B entities.

According to a November 2022 report by the American Hospital Association, these unlawful actions by drug companies to deny discounts have increased drug costs on the average critical access 340B hospital by $500K annually and have increased drug costs by more than $3 million annually for the average DSH 340B hospital. Some of our members report a significantly higher impact, such as one critical access hospital that is paying $1.2 million in higher drug costs due to new contract pharmacy restrictions alone. Additionally, a September 2022 report from the Office of the Assistant Secretary for Planning and Evaluation found that drug prices increased more than thirty percent between July 2021 and July 2022, more than 3X the rate of inflation (8.5%). Some drugs increased in price by more than $20,000 or 500%.

Similarly, WHA appreciates the provisions protecting 340B covered entities from having their 340B discount savings pocketed by pharmacy benefit managers. A growing number of PBMs have notified 340B hospitals in Wisconsin of reductions in reimbursements for drugs the hospital receives at a 340B discount while continuing to pay the same reimbursement rate for non-340B entities. This essentially diverts the savings Congress intended for 340B covered entities to PBM middlemen. While 340B entities like hospitals use 340B savings to improve health care services in the communities by offering services like free or low-cost dental and primary care clinics, behavioral health services, and remote RX dispensing sites in rural areas, there is no evidence that PBMs divert these savings for anything other than padding their bottom lines.

Congress Should Not Place Burdensome Restrictions on Contract Pharmacies

As we have seen over the last few years, drug companies will use every trick in their arsenal to obstruct the 340B program. For this reason, we believe Congress should employ stronger overall language to close any possible loopholes drug companies would use to restrict or deny discounts at contract pharmacies.

Additionally, WHA opposes burdensome and unnecessary requirements that will not serve a benefit to patients. This includes proposed requirements to annually reregister contract pharmacies that have previously been registered, as well as proposals to submit and register each and every contract. This is entirely unnecessary since the covered entity (CE) is ultimately responsible for compliance and the staff time and other resources necessary both for CEs to provide this data and for the government to review it would be immense, while offering little if any benefit to the program. Furthermore, contract arrangements are already registered with HRSA and publicly available.

WHA also opposes having contract pharmacies subject to audits, as this could be a backdoor way to discouraging participation in the 340B program. Again, 340B CEs are ultimately responsible for compliance and subject to their own audits so there appears to be little benefit to this proposed regulation.

WHA and our members are also concerned about geographic restrictions on contract pharmacies. For instance, many of our members are rural, and one such rural member reported concerns that there are no close specialty pharmacies. Therefore, placing a geographic limitation could restrict the ability for rural 340B hospitals to receive specialty drugs at a 340B discount. Even urban members must contend with the fact that insurers often steer patients to their preferred (often owned) specialty pharmacies which could further limit access. This shows how geographic restrictions could have enormous financial consequences given the

substantial costs such drugs bear and the fact that specialty pharmacies may account for around 50% of the drug market.

WHA Supports HRSA's Existing Flexible Patient Definition

Because the delivery of health care services is constantly evolving, WHA supports maintaining the existing HRSA definition of a 340B patient. Telehealth is one example of an innovation in care delivery that came after the advent of 340B, and yet, HRSA has been able to allow 340B policy to continue to align with evolving care delivery. This must continue; we have seen too often how inflexible statutes do not keep up with the times.

Another concern brought to WHA from one of its members is how HRSA proposed changing the patient definition in 2015 in a way that would restrict referrals 340B hospitals receive. This particular rural hospital would lose nearly 1/5th of its 340B benefits if this restriction went into place, and it also noted that around half of the patients it serves from referrals are those seeking cancer drug infusions.

Congress Should Not Over-Regulate Child Sites

WHA cautions Congress not to restrict child sites based on them being wholly owned by the parent entity. While this may often be the case, hospital and provider group relations are constantly evolving and this could unfairly restrict 340B discounts.

Further, WHA members have expressed concerns about limiting discounts based on child sites offering a meaningful range of services. Many of our provider-based locations often specialty services targeted to a particular type of patient or needs of the community and this definition seems too ambiguous and could unintentionally restrict access to 340B discounts.

Lastly, while this could apply to child sites in general or main 340B entities, WHA members have expressed concerns about orphan drug exclusions in the 340B program. Orphan drug exclusion can be difficult for rural 340B sites given the high expense and low margins of such sites. It is also challenging to determine whether certain drugs have orphan designations. Add in the fact that the draft legislation proposes new audits for hospitals claiming discounts on drugs that are not covered outpatient drugs, and the ambiguity in determining whether those drugs are in fact orphan drugs, and this could create serious confusion and financial losses for such rural hospitals.

Congress Should Remove Burdensome Regulations that Provide Little Value

WHA and its members are committed to transparency and have shown this commitment in their adherence to, for example, recent federal hospital price transparency regulations. It is also important to remember that hospitals already report a variety of information publicly, such as uncompensated care, charity care, and other community benefits which are listed on Medicare cost reports and the IRS 990 forms that tax exempt organizations must file.

Unfortunately, some of the proposed additional 340B reporting requirements would be extremely burdensome and would not benefit the program or regulators. WHA does not support requiring each child site to report on their share of the charity care provided by the covered entity and in comparison to operating costs, as we have heard multiple concerns from our hospitals regarding this. Offsetting charity care or uncompensated care is not the only way hospitals use savings from the program. For example, our members utilize savings to offset losses in other areas of their mission such as nursing homes that serve their patients but run at a loss. Furthermore, requiring each child site to report on this would be more administratively burdensome than just having the CE report it.

WHA members are also concerned that the savings the legislation attempts to have CEs report uses a flawed metric. Hospitals routinely purchase a large share of prescription drugs through group purchase orders (GPO) which help them obtain such drugs at a lower cost than wholesale acquisition cost (WAC). Therefore, stating savings based on the difference between WAC and 340B discount would grossly overstate savings. For example, one WHA member reported that the repayment of Ozempic 4mg/3mL pen would be $801.62 using WAC versus $583.61 using GPO.

WHA members also have concerns about reporting this information on a Medicare Cost Report, given that those are regulated by an entirely separate federal agency. Furthermore, it may not be administratively possible to distinguish between Medicaid and CHIP recipients given that the State of Wisconsin combines the program. Lastly, the requirement that entities break out 340B participants in a Health Professional Shortage Area (HPSA) would be administratively complex, especially since HRSA's data modernization project continues to change HPSA boundaries.

In addition to these concerns, WHA is concerned that these "transparency" requirements are solely focused on hospitals. When drug companies are the other half of the 340B program, it is curious that there are no requirements for them to report on how prices are set, by how much they are increasing their prices and under what rationale, or why they may be implementing polices to restrict access to 340B discounts.

Congress Should Not Expand Audit Standards or Audits of Contract Pharmacies

WHA does not support proposals to expand audits to contract pharmacies. As previously stated, this could discourage their participation in 340B, and audits of CEs which are ultimately responsible for 340B compliance should suffice. Furthermore, WHA opposes removing the current audit standards of "knowing and intentional" violations that are "systemic and egregious." Hospitals are already charged with complying with the federal Stark Law which for years has had a chilling effect on participation in value-based care due to it being a strict liability law meaning that unintentional violations can carry millions of dollars of fines. We should not repeat a similar mistake with 340B.

Furthermore, like our comments in the preceding section, it is curious that the draft proposes only to expand audits of CEs and contract pharmacies, but not drug companies. Program integrity requirements should cut both ways. For instance, drug companies sometimes overcharge, deny discounts, or place drugs in limited distribution. Yet, drug companies can audit hospitals, but not vice versa. If Congress is expanding oversight, that expansion should propose equal program integrity for CEs and drug companies.

Duplicate Discounts

WHA is generally supportive of efforts to establish a third-party national claims clearinghouse to prevent duplicate discounts. This requires the cooperation of State Medicaid agencies as WHA members currently have no certain way to avoid duplicate discounts where Medicaid managed care organizations (MCOs) policies (such as claims modifiers) do not always align. Until that is up and running (and assuming it works), CEs should not be held financially responsible for duplicate discounts that arise on account of states utilizing MCOs.

WHA also has concerns about proposals to require CEs to submit all-payer claims data to prevent duplicate discounts. This data is unnecessary to prevent duplicate discounts and drug companies will undoubtedly use such data to their already sizable financial advantage.

WHA is also concerned that the discussion draft appears to set a new floor for hospital financial assistance policies at 200% of the federal poverty level rather than allowing hospitals to adapt their policies to the needs of the communities they serve as the agency that governs these policies (the IRS) currently allows.

WHA Opposes the Newly Proposed User Fees for Covered Entities

WHA is concerned about the new funding mechanism that has been proposed in the draft legislation which would be paid for by hospitals. Given that the program was designed to help hospitals stretch scarce federal resources, this requirement would detract from their ability to do so.

WHA greatly appreciates the opportunity to share our comments. Thank you for all the work you are doing to generate ideas that strengthen and protect the 340B program.

Sincerely,

Eric Borgerding
President & CEO