WISCONSIN HOSPITAL ASSOCIATION

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5510 Research Park Drive
P.O. Box 259038
Madison, WI 53725-9038
608.274.1820 | FAX 608.274.8554 | www.wha.org

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 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 340B.

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 Wiscconsin. A little more than half (81) of Wisconsin's 150 hospitals participate in the 340B prescription drug program.

Indeed, the fact that so many hospitals do not currently participate in a program that would lower their drug costs shows that the program is not overutilized by hospitals and is truly reserved only for safety-net hospitals. Hospitals must be either critical access hospitals (CAHs), cancer hospitals, children's hospitals, government-affiliated hospitals, or serve a disproportionately high (DSH) share of Medicaid patients.

In fact, some hospitals that one would expect to qualify for the 340B program based on their low mixture of private/commercially insured patients compared to their high mixture of Medicare and Medicaid patients, report that they are reluctant to enroll in the program for fear that year-to-year variations in payer mixes would jeopardize their ability to consistently remain in the program. The program includes a high bar for entry and it is not necessarily worth the risk to invest such resources in the program if the savings cannot be guaranteed on a long-term basis.

WHA and its members strongly support sensible measures to ensure policymakers and the public have confidence in the integrity of the 340B program. At the same time, policy makers should be wary of putting additional, unnecessary burdens on a health care industry that already suffers from too much regulation.

It is important to remember that 340B discounts themselves do not come from taxpayer funding, but rather, discounts from drug manufacturers. Congress established the program this way recognizing in part that it was already underpaying hospitals for the cost to provide Medicare services. When WHA analyzes our members publicly available cost report data, we find that on average, Medicare pays Wisconsin hospitals only 73 percent of what it costs to care for Medicare patients and approximately 67 percent of what it costs to care for Medicaid patients.

Given this disparity, Congressional report language from inception of the 340B program states that it should "help hospitals stretch scarce federal resources as far as possible." If hospitals are required to treat Medicare and Medicaid patients and receive less than their true costs under Medicare and Medicaid, then it is not unreasonable to similarly require drug manufacturers to sell their outpatient drugs to hospitals at a discount in exchange for their ability to sell their drugs under these programs.

Question: What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

WHA believes the Health Resources and Services Administration (HRSA) has ample authority from Congress to oversee the 340B program and ensure program integrity. We believe there are opportunities to use this existing authority in a way that better serves participants in the program. We recognize there is a desire from some to give HRSA additional staffing and resources to increase their oversight role. While we are not necessarily opposed to such ideas, we believe these efforts should be measured and ensure the proper balance to include a level playing field for drug manufacturers and covered entities such as hospitals, community health centers, and HIV/aids clinics.

Hospitals are already one of the most heavily regulated industries in the country. In 2017, the American Hospital Association came out with a report on hospitals' excessive regulatory burden and found a number of alarming examples of how regulation is harming hospitals and increasing costs for patients. It found, among other things, that:

- Health systems, hospitals and post-acute care providers must comply with 629 discrete regulatory requirements across nine domains.
- Health systems, hospitals and PAC providers spend nearly $39 billion a year solely on the administrative activities related to regulatory compliance in these nine domains.
- An average size hospital dedicates 59 FTEs to regulatory compliance, over one- quarter of which are doctors and nurses.

These regulations have only grown in the six years since and it is imperative that we do not grow unnecessary regulations further, but rather, first fully utilize existing authority agencies have.

Perhaps one of the ways HRSA can better exercise its existing oversight authority is to utilize the Administrative Dispute Resolution (ADR) process in the way Congress intended it to be used. Through the thirteen years the program has existed, it has not functioned as a proper way for the agency to enforce disagreements between covered entities and drug manufacturers. WHA strongly supports HRSA finalizing its recent proposed rule on the ADR process. It is also important to recognize the role the office of the inspector general (OIG) has in enforcing program integrity measures. HRSA and OIG should work together to the fullest extent possible to enforce 340B statutes and rules.

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

WHA and our members have been particularly frustrated by drug manufacturers clear violations of the 340B program in terms of denying or severely restricting discounts for drugs dispensed through community contract pharmacies. We fully support utilizing the ADR process mentioned in the previous section as one tool to resolve these disputes. The OIG should also be free to use its authority to enforce these program requirements.

According to a November 2022 report by the American Hospital Association, these unlawful actions by drug companies 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%.

Drug companies are not using their extra profits to increase access to medications. In fact, during this same time period, there have been persistent reports of prescription drug supply chain shortages for everything ranging from ADHD medications to cancer treatments. These drug shortages are having very real negative impacts on patients and the hospitals and health care providers that treat them.

The discounts hospitals receive under the 340B program are one of the few tools hospitals have to offset these otherwise unchecked growth in prescription drug costs. While HRSA has admirably attempted to use civil monetary penalties to force drug companies to honor discounts at contract pharmacies as required by the 340B program, drug companies have used their vast resources to file lawsuits to block HRSA's actions. At least one court of appeals has ruled that its interpretation of the statute is that HRSA does not have the authority to compel drug companies to follow HRSA's long-standing policy on contract pharmacy discounts***. Therefore, Congress should clear up any confusion by clarifying explicitly in statute that contract pharmacies are an extension of the 340B program and that drug companies may not deny or restrict these discounts for hospital patients receiving their drugs from a contract pharmacy.***

Question: 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?

WHA has become increasingly concerned over discriminatory actions some pharmacy benefit managers (PBMs) have been taking recently to pocket the savings intended for 340B covered entities. Specifically, some PBMs have notified 340B hospitals in Wisconsin that they will be reducing 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.

Some PBMs or health insurers have also engaged in practices such as "whitebagging" or "brownbagging" that harm patient care. These policies require patients to obtain prescription drugs like injectables or cancer infusion drugs from a PBM or insurer's preferred source rather than the patient's in-network hospital pharmacy. WHA has collected patient stories about how these policies have led to surprise out-of-network bills, or even worse, delays in treatment that can be extremely stressful for patients who are undergoing treatment for life-threatening illnesses.

Congress should explicitly protect patients and 340B covered entities from both of these discriminatory practices by making it illegal for PBMs to either provide differential discriminatory reimbursement or steer patients away from 340B pharmacies to their own pharmacies. These protections are included in H.R. 2534, the **PROTECT 340B Act**, bipartisan legislation WHA supports. Congress should further prohibit PBMs and insurers from forcing patients or health care providers to accept dangerous "whitebagging" or "brownbagging" policies.

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

WHA supports having appropriate guardrails against duplicate discounts. Hospitals already devote significant resources to guard against such duplicate discounts. WHA supports a national data claims clearinghouse by a neutral third party that would be free of conflicts of interest. The goal of this clearinghouse would be to collect and review data from state Medicaid agencies and covered entities to further prevent duplicate discounts. It is important that this be a third party, and not left up to the drug manufacturers, some of whom have tried to use this issue as leverage to limit lawful 340B discounts. Furthermore, the entity must limit the reporting burden on covered entities and ensure the data is secure and in accordance with HIPAA standards hospitals are already required to follow.

Question: What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

The 340B program already has an entire cottage industry dedicated to helping covered entities comply with its various requirements. Hospitals already undergo extensive internal audits and are required to ensure they are not receiving duplicate discounts from state Medicaid programs (as mentioned above) or diverting drug to ineligible patients. In fact, there seems to currently exist an uneven playing field in terms of requiring more transparency of covered entities than drug manufacturers.

HRSA, and to a degree, drug manufacturers already have authority to audit covered entities. HRSA conducts over 200 audits of 340B hospitals annually while at the same time conducting only six audits of drug manufacturers. Hospitals must maintain several years of auditable records, and they often end up contracting with various entities to assist with the significant compliance requirements. Yet, hospitals have little recourse and no ability to audit drug manufacturers and to date, the ADR process previously mentioned has been of very limited utility.

One idea that could merit further consideration would be to allow HRSA to set up standards for hospital internal audits that it would deem to be in compliance with HRSA-level audits. Hospitals are already used to having entities like The Joint Commission that act on behalf of HHS when surveying hospitals and perhaps a similar process would allow a more efficient use of existing resources to better satisfy program integrity while freeing up resources for HRSA to level the playing field in terms of auditing drug manufacturer compliance.

Question: 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?

In the same vein as our response to other questions, we ask Congress to consider the extensive reporting hospitals are already required to do before asking for additional, unnecessary reporting requirements. While hospitals are not by any means against robust transparency, it is important to guard against overregulation of an industry that is already one of the most heavily regulated industries. While hospitals would no doubt find a way to comply with additional regulations, that compliance will nearly always come at a cost and divert valuable resources that hospitals would rather dedicate to direct patient care.

It is important to remember that hospitals already report a variety of information publicly. For instance, they report uncompensated care, charity care, and other community benefits on Medicare cost reports and the IRS 990 forms that tax exempt organizations must file.

Sadly, some groups have tried to understate the impact of hospitals' contributions to their local communities by cherry picking numbers such as only the uncompensated care hospitals report. Wisconsin is fortunate to be a state that is typically among the top-ten in the country in terms of having a low uninsured rate. Since uncompensated care is mainly a measurement of the uninsured that hospitals serve, it fails to take into consideration that states like Wisconsin which have a high uninsured rate also typically serve a higher proportion of Medicaid beneficiaries. Wisconsin hospitals take significant losses on Medicaid patients, as the state only reimburses approximately 67% of what it costs hospitals to care for Medicaid patients. It is vitally important that this fact is considered when assessing community benefits hospitals provide.

Congress must be careful to balance desires for additional transparency requirements with the impact and cost such requirements would have on covered entities, and whether such reporting metrics would benefit patient care. Notably missing from most transparency discussions are proposals to increase transparency on how drug companies set their prices, as well as whether drug manufacturing policies and tactics are at all to blame for persistent drug supply chain shortages. We firmly believe the goal of the program should continue to be to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. It seems better understanding the role of drug manufacturers' pricing policies would help further advance that goal.

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