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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 Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

RE: 340B Drug Discount Program Request for Information

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

On behalf of the nation's children's hospitals and the patients and families we serve, thank you for the opportunity to provide comments on the request for information (RFI) on the 340B Drug Discount Program. We appreciate your interest in strengthening the 340B program and urge you to consider the program's value for children, who represent 25% of the total U.S. population. We strongly support efforts to strengthen the program to ensure that our nation's most vulnerable patients have access to needed medications.

The more than 200 children's hospitals that comprise the Children's Hospital Association (CHA) are dedicated to the health and well-being of our nation's children. Children's hospitals advance child health through innovations in the quality, cost and care delivery—regardless of payer—and serve as a vital safety net for uninsured, underinsured and publicly insured children. Medicaid, on average, provides health insurance coverage for one-half of children's hospitals patients; in some children's hospitals, Medicaid covers closer to three-quarters of their child patients. Though children's hospitals account for only 5% of hospitals in the U.S., they account for about 45% of all hospital days for children on Medicaid. We are regional centers for children's health, providing highly specialized pediatric care across large geographic areas.

The 340B program supports children's hospitals in their mission to serve low-income and underinsured children regardless of their insurance status. Children are largely insured by Medicaid and the Children's Health Insurance Program, but children's hospitals qualify for 340B because a significant shortfall exists between the cost of care and Medicaid payment. Children's hospitals depend on the 340B program to provide vulnerable patients with access to life-saving medications. Congress expressly recognized the important role of children's hospitals in providing access to these medications by adding them to the list of 340B-eligible entities.

The financial support provided by the 340B program—the result of pharmaceutical manufacturers reducing outpatient drug prices and involving no direct congressional appropriation—enables children's hospitals to help more vulnerable patients, improve access to care and provide more comprehensive services, many times the only source of these services and supports in the community. For example, some hospitals have used the savings to partially subsidize the cost of providing behavioral health services, annual flu vaccinations, affordable prescription drugs or hemophilia treatment centers. The program has been a critical resource for children's hospitals in helping offset low Medicaid reimbursement rates and enabling them to further stretch resources to support initiatives that provide essential care to children and their families. We believe that the 340B program is working as intended to help safety net providers, including the more than 50 children's hospitals that take part in the program.

Our response to the RFI focuses on considerations that must be addressed to strengthen and stabilize the 340B program to help ensure that our nation's children continue to have access to safe and effective health care, including needed drugs. Below please find our detailed responses to specific questions in the RFI.

1. What specific policies should be considered to ensure Health Resources and Services Administration (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?

We encourage Congress to expand HRSA's authority to oversee and enforce 340B regulations, but these authorities should be specifically focused on measures that strengthen and stabilize the program. For instance, we support HRSA having greater oversight of drug manufacturers to ensure they sell 340B covered outpatient drugs without restrictions to covered entities with contract pharmacy arrangements.

HRSA's existing regulatory authority does not allow it to address key aspects of the program, such as contract pharmacy arrangements. For the last three years that lack of regulatory authority has resulted in several of the largest drug manufacturers restricting 340B hospitals' access to the statutorily required 340B prices for drugs purchased through established arrangements with community and specialty pharmacies. Without access to 340B drugs at these pharmacies, children can experience delays in receiving necessary health care services, potentially resulting in medical emergencies or negative health outcomes.

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

We encourage Congress to strengthen and clarify the requirements for drug manufacturers to offer 340B pricing and sell drugs to covered entities without restrictions. More than 20 pharmaceutical companies are imposing overly burdensome requirements while multiple pharmaceutical manufacturers have taken steps to restrict 340B contract pharmacy arrangements. For instance, some manufacturers have requested 340B claims data from covered entities' contract pharmacies, which can be a burdensome process. Children's hospitals utilize contract pharmacies to help patients more easily access medications within their communities. Children and their families often rely on contract pharmacies since pediatric specialty care often is not located near their homes. Manufacturers' limits on contract pharmacies and other harmful practices can impede timely access to needed medications for children, especially those with medical complexities who need specialty drugs.

3. 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?

We encourage Congress to work with CMS on ways to prohibit payers' ability to use delivery methods that compromise patient care and can lead to inadequate provider reimbursement for 340B providers. No federal protections exist to prohibit payers from implementing policies that discriminate against providers based on their 340B participation. Examples of payer policies that directly or indirectly discriminate against 340B providers include lower reimbursement based on 340B participation, 340B claim identification requirements and mandatory "white bagging" requirements.

Implementing claim identification requirements often requires a massive investment of financial resources and the need for manual updates of millions of claims on a regular basis. When a manufacturer mandates white bagging, obtaining the appropriate medications becomes a time-consuming and complicated endeavor. White bagging has caused a multitude of issues for patient families and the providers who care for them—from medication procurement to drug delivery to patient safety and care. Issues with delivery and the increased need for provider and patient engagement in this process creates an undue hardship on pediatric patients—especially for those with complex medical conditions—and their families who may have made schedule and other accommodations to travel to a site to receive a drug, only to find that it is not available due to white bagging-related delays.

Furthermore, we recommend that Congress work with CMS to prohibit payers from removing 340B providers from the payer's network solely because they participate in 340B, or taking any action that would interfere with the covered entity's ability to use 340B for its eligible patients.

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

We encourage Congress to ask CMS to promote state adoption of a retroactive claims identification model. State Medicaid agencies are empowered to enact policies to ensure that Medicaid rebates and 340B discounts are not taken on the same claim. However, in many states these policies are inconsistent and difficult for many covered entities to implement.

Oregon is a state that has implemented a successful model. The Oregon model requires covered entities to submit claims data retroactively, which the state's rebate vendor uses to remove those claims from the state's rebate requests. The program involves only the provider and the Medicaid vendor, making it easy to implement and audit, since the information does not have to go through pharmacy benefit managers, insurers or other entities. The Oregon model demonstrates that retrospective 340B claim identification is achievable without the use of 340B identifiers on claims. We encourage Congress to work with HHS on contracting with a third party to collect and review data from state Medicaid agencies and covered entities to prevent Medicaid duplicate discounts, similarly to the successful duplicate discount prevention method adopted in Oregon.

5. 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?

We encourage Congress to change child site registration requirements to only include the physical sites where 340B drugs are delivered and not the individual clinics located within each site. HRSA currently requires all the clinics that

utilize 340B within a physical child site location to be registered individually. This requirement can be an especially burdensome process for children's hospitals, which often have multiple clinics and services—such as an emergency room, observation beds and clinics—within one physical location. Under current policy, a hospital is required to register all of these clinical services, even though they are situated within the four walls of the same facility.

We also recommend that Congress encourage HRSA to offer more flexibility when determining who can access agency information that would help covered entities better implement the 340B program. Currently, only the authorizing official and primary contact can log into the Office of Pharmacy Affairs Information System (OPAIS) database, which covered entities must access to update and confirm the accuracy of information on 340B pricing, child sites, and contract pharmacies during registration and recertification. It would be helpful if HRSA allowed the authorizing and primary to designate key internal 340B entity leaders read-only access to this information to help improve implementation of the program and oversight over manufacturers.

6. 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?

Children's hospitals support efforts to enhance 340B program integrity. We encourage Congress to work closely with the children's hospital community to discuss the impact of potential changes to transparency requirements. Any proposal should take into consideration existing hospital reporting requirements, as children's hospitals are already subject to 340B oversight by multiple government entities. In addition to the annual recertification and ongoing audits by HRSA, children's hospitals also annually submit cost reports to Medicaid agencies and report financial assistance and community benefits to the Internal Revenue Service.

Thank you again for the opportunity to provide feedback. We look forward to working with you to ensure that the 340B program continues to provide access to needed health care services for children. Please contact Natalie Torentinos at Natalie.Torentinos@childrenshospitals.org or (202) 753-5372 should you need more information.

Sincerely,

Aimee Ossman
Vice President, Policy
Children's Hospital Association