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

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 discussion draft, *Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B Act*, and supplemental request for information (RFI). We appreciate your interest in strengthening the 340B program and strongly urge you to consider issues unique to pediatric health care as you address contract pharmacies, patient definition, child sites, transparency, duplicate discounts, and user fees. We are particularly concerned about whether the proposed transparency requirements meaningfully capture the benefits children's hospitals provide to their surrounding communities and their role in providing care to children on Medicaid.

It's critical that appropriate metrics are used to evaluate how pediatric patients benefit from the 340B program, because children are largely insured by Medicaid, the Children's Health Insurance Program (CHIP), or private insurance. Approximately 95 percent of children aged up to 17 years old are insured.[1] 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.

The more than 200 children's hospitals that comprise the Children's Hospital Association (CHA) serve as a vital safety net for uninsured, underinsured and publicly insured children. Children's hospitals qualify for 340B because a significant shortfall exists between the cost of care and Medicaid payment. The 340B program has been a critical resource for children's hospitals in enabling them to further stretch resources to support initiatives that provide

[1] Health insurance coverage: Early release of estimates from the National Health Interview Survey, 2022 (cdc.gov)

essential care to children and their families. **We believe that the 340B program is working as intended to help safety net providers, including children's hospitals that are part of academic and larger healthcare systems, and the more than 50 self-governing children's hospitals that take part in the program.** 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 in 2006.

Children's hospitals depend on the 340B program to provide children from low-income families with access to life-saving medications. The financial support provided by the 340B program enables children's hospitals to help more low-income 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.

Our response to the discussion draft 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 medications. Below please find our detailed responses to the discussion draft provisions and some specific questions in the RFI.

Section 3. Contract Pharmacies

We appreciate the discussion draft's proposal that prohibits drug manufacturers from restricting access to 340B discounts at contract pharmacies. We support requiring manufacturers to offer 340B discounts for an outpatient drug without conditions, regardless of whether the drug is dispensed at a contract pharmacy or an in-house pharmacy. 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. Children and their families, especially those with complex medical conditions, frequently rely on contract pharmacies since pediatric specialty care often is not located near their homes. Limitations to contract pharmacy arrangements would greatly limit children's hospitals' ability to provide quality health care services to the pediatric population.

To further strengthen this section, we urge you to modify the proposal that requires covered entities to annually register all contract pharmacy arrangements with the HHS Secretary. Annual registration should only be required for new contract pharmacy arrangements that have been established in the preceding year. Children's hospitals would have to devote significant staff time and resources to review every such contract, creating indefinite delays that could jeopardize their ability to provide 340B medications for pediatric patients in a timely manner.

What policies would allow covered entities to contract with pharmacies to ensure patients have access, without additional requirements or limitations?

We caution against imposing any geographical limits on contract pharmacies. It is imperative that our hospitals' care capacity continues to be supported by contract pharmacy arrangements so that every community – including communities without a children's hospital - can provide 340B medications that are essential for quality pediatric care. It is not uncommon for children, particularly those with medical complexity or specialized health care needs, to travel out of their community, region, or state to receive the care that can only be provided at a children's hospital. **Contract pharmacies allow for ongoing access to needed medications when children and their families do not live near a children's hospital, allowing them to stay at home during a long-term treatment or recovery period, which can be beneficial for the pediatric patient and their family.**

In addition, we ask that no limitations be placed on a contract pharmacy even in circumstances when a hospital utilizes an in-house retail pharmacy. Pediatric patients should not be restricted to accessing vital medications only through in-house pharmacies if that facility does not meet their specific health care needs. The in-house pharmacy's location might present travel limitations to children and their families, or the pharmacy might not provide medications to treat certain rare or complex conditions.

A greater number of 340B medications are now specialty medications, which can often only be obtained through specialty pharmacies. How would you structure any limitation on contract pharmacy while also ensuring patients have access to these specialty medications?

We caution against placing any limitation on covered entities' use of contract pharmacies, especially for pediatric patients who need access to specialty medications. Manufacturers' limits on specialty pharmacies and other harmful practices can impede timely access to needed medications for children, especially those with medical complexities who need specialty drugs.

For instance, some manufacturers restrict covered entities' designated contract specialty pharmacies to only one facility, or require they be located within a 40-mile radius. There are far fewer specialty pharmacies than retail pharmacies across the country due to complex procedures and strict accreditation requirements, and even fewer pediatric specialty pharmacies. The high-cost specialty medications these pharmacies provide offer some of the most life-altering benefits to pediatric patients. The scarcity of these facilities can often make it difficult for a children's hospital to find pediatric specialty pharmacy partners.

Children are constantly growing and developing. Pediatric care requires specialized medications, as well as specialized care that includes extra time, monitoring, and health care providers who understand kids of all ages and from all backgrounds. The comprehensive care provided by pediatric specialty pharmacies accounts for all aspects of a pediatric patient's development, including delivery, risk of handling and professional services. Disruptions in their care – especially for children with complex medical conditions - can have a significant negative impact on children's mental and physical health and their long-term well-being.

Section 4. Patient Definition

We support the Health Resources and Services Administration's (HRSA) current enforcement of the 1996 patient definition guidance and believe this issue does not necessitate legislation. If Congress establishes a new standard for eligible patient, we recommend that it be focused only on elements that strengthen and stabilize the program for pediatric patients.

For example, a codified patient definition should not jeopardize the use of telehealth or any other future health care delivery method for 340B eligible patients. The 1996 guidance is flexible enough to include an established relationship with covered entities through telehealth, even though this mode of health care delivery did not exist when the guidance was released. Telehealth has played a critical role in addressing some of the constraints that children and their families face accessing care due to geography—particularly in rural and other underserved areas. It also has allowed children with special health care needs or complex conditions, including technology-dependent children, to forgo long and complicated trips to one or more facilities and to connect with providers located outside of their home state.

Furthermore, we caution against incorporating HRSA's proposed guidance in 2015, which would have limited 340B use to only those drugs ordered as part of a service provided by the covered entity. A more restrictive patient definition that excludes referral patients would be devastating to a children's hospitals' 340B program and their ability to provide high-cost medications to patients. The 2015 guidance was overly restrictive and was eventually withdrawn following significant opposition by the covered entity community.

Section 5. Child Sites

As you consider proposals that shift away from the current child site registration system, we urge Congress to require that future guidelines offer flexibility for children's hospitals and enhance the scope of child sites in the 340B program—without ambiguous requirements that are burdensome or unnecessary.

To that end, we are concerned about the draft's proposal to require a child site to provide a "clinically meaningful range of services" since these services are not defined. One of the strengths of the 340B program is the flexibility it affords to covered entities like children's hospitals to tailor their programs and services to the communities they serve. This arbitrary requirement would potentially constrain our hospital's child sites ability to meet the unique needs of pediatric patients. Requiring 340B-eligible child sites to offer an excessively broad list of services could possibly limit health care access for children who utilize our hospitals' outpatient sites. Some of our hospital's child sites consist of a single clinic that focuses on treating one condition.

In addition, we encourage Congress to consider only requiring registration of the physical child sites where 340B drugs are delivered and not the individual clinics located within each site. The added logistical and financial barriers of the current registration process may impact a children's hospital's decision about the feasibility of opening a child site location. Registering individual clinics can be an especially burdensome process for children's hospitals, which often have multiple clinics and services—such as endocrinology or gastrointestinal 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.

Section 6. Transparency

Children's hospitals are committed to efforts that enhance 340B program integrity. As we mention above, we strongly believe that appropriate transparency metrics must be able to define how 340B savings benefit pediatric patients. These measures should be meaningful and accurate and not impose unnecessary burdens on children's hospitals.

For these reasons, we strongly oppose the draft's proposals that use charity care to evaluate 340B. **Proposals that require charity care reporting—particularly charity care for only the uninsured versus the underinsured—unfairly punish children's hospitals.** Due to programs like Medicaid and CHIP, the vast majority of children in the nation are insured. Therefore, **charity care reporting does not capture the benefits children's hospitals provide to the patients and communities they serve or account for the significant shortfall between the cost of care and Medicaid payments.** Children's hospitals have a longstanding commitment to provide care for lower income children regardless of ability to pay and have a disproportionally high amount of undercompensated care, particularly from Medicaid shortfalls in payments to the hospital and our physicians.

In addition, we are concerned about requiring covered entities to detail the percentage of patients who reside in Health Professional Shortage Areas (HPSAs) and Medically Underserved Areas (MUAs). The current HPSA and

MUA designations do not adequately reflect the reach of children's hospitals and their staff into these underserved neighborhoods. HPSAs and MUAs are specific geographic areas determined largely on the basis of access to adult primary care services, not to the pediatric specialty services that children's hospitals provide. Furthermore, it is not uncommon for children, particularly those with medical complexity, to travel out of their community, region or state to receive the extremely specialized care that can only be provided at a children's hospital. As a result, the process for acquiring this information would be administratively complex for children's hospitals, and the necessary tools to track patients who live in HPSAs and MUAs are not readily available. Accessing this information would greatly burden children's hospitals and inhibit their ability to effectively manage 340B programs and provide care to pediatric patients.

Furthermore, we caution against requirements to describe how the 340B discount is used when the draft's definition of the discount is the difference between 340B actual acquisition cost and the wholesaler acquisition cost (WAC) price. For most covered outpatient drugs purchased by children's hospitals, the price paid outside of the 340B program is a group purchasing organization (GPO) price or similar price. It is important to employ definitions of 340B savings that do not overstate the true savings achieved by children's hospitals.

As Congress considers ways to ensure 340B program accountability, we encourage you 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.

Section 8. Preventing Duplicate Discounts

We are concerned about requiring covered entities to participate in a national data clearinghouse to prevent duplicate discounts and seek clarification on this process. Implementing claims identification requirements would require a massive investment of financial resources and the need for manual updates of millions of claims on a regular basis. Imposing additional claims data reporting would be duplicative and create an unnecessary burden for children's hospitals.

As an alternative, we encourage Congress to ask CMS to promote state adoption of a retroactive claims identification model to prevent duplicate discounts. Oregon is a state that has implemented a successful model that 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.

Section 10. User Fee Program

We oppose the discussion draft's proposed calculation of the user fee—0.01% of a covered entity's 340B savings—because the draft's definition of 340B savings is based on the difference between 340B cost and WAC price. As we mention above, the difference between 340B cost and WAC will overstate children's hospitals' actual 340B program savings. It is important to employ a 340B discount definition that do not misstate or confuse the true savings achieved by 340B children's hospitals.

If you move forward with a user fee program, we encourage you to work with the children's hospital community on a user fee calculation that incorporates an accurate estimate of 340B savings. Our hospitals calculate 340B savings as the difference between the 340B cost and the GPO or self-negotiated price. The most accurate estimation is the difference between 340B cost and GPO price, then assessing the impact of forced WAC purchasing due to instances when hospitals are barred from buying drugs through GPOs.

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 C. Ossman
Vice President, Policy
Children's Hospital Association