



Children's Hospital Association Statement for the Record

U.S. House Energy and Commerce Subcommittee on Oversight and Investigations Hearing, "Oversight of 340B Drug Pricing Program" June 4, 2024

On behalf of the nation's over 200 children's hospitals and the children and families we serve, we write to express our strong support for the 340B program. The Children's Hospital Association (CHA) urges Congress to protect the program and ensure that patients have access to important, life-saving drugs. We encourage the committee to work with provider stakeholders to further enhance the effectiveness and integrity of the 340B program, ensuring its continued ability to support pediatric patients nationwide. We oppose efforts that would diminish the value and scope of the 340B program and look forward to ensuring the 340B program remains strong for the pediatric patients and communities 340B hospitals serve.

The 340B program is vital to supporting children's hospitals' mission to serve low-income and underinsured children regardless of their insurance status. 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.** 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. The 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 children, 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 54 self-governing children's hospitals that take part in the program, to serve low-income, uninsured, and underinsured pediatric patients.

Below please find the 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.

Children's Hospitals and 340B

Transparency

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. 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.

We strongly oppose using 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.**

Any legislative proposal should consider 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.

Contract Pharmacies

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 which could restrict children's access to needed medications. 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.

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.

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.

Child Sites

We support enhancing the scope of child sites in the 340B program without ambiguous requirements that are burdensome or unnecessary. **To that end, 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.

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 patients, 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.

HRSA Oversight

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.

We ask that Congress consider the recommendations we have laid out to strengthen and improve the program and reject legislative efforts threatening the effectiveness of the 340B program.

340B ACCESS Act

We are deeply concerned about the recently introduced *340B Affording Care for Communities and Ensuring a Strong Safety-Net Act*, or 340B ACCESS Act, which is a bill that poses significant threats to the 340B program and, by extension, to the children served by children's hospitals.

The 340B ACCESS Act would impose severe restrictions on hospitals' ability to utilize 340B drugs, including bans on using 340B drugs for insured children (with limited exceptions), discharge prescriptions, referrals or telehealth, and at certain child sites. It would also impose limits on the number of contract pharmacies and require that 340B savings not exceed charity care levels. These provisions would decimate the resources that enable crucial care and eliminate effective curbs on drug price hikes for 340B and non-340B drugs alike.

It is imperative that efforts to oversee the 340B Drug Pricing Program are comprehensive, collaborative, and responsive to the needs of pediatric patients and their families. By ensuring transparency, fostering innovation, and promoting equitable access to life-saving medications, we can uphold the integrity of the 340B program and safeguard the health of our nation's children. Children's hospitals remain steadfast in our commitment to collaborate with you in advancing policies that prioritize the well-being of our youngest citizens and make tangible improvements in their lives.