Illinois Health and Hospital Association

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart 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 200 hospitals and nearly 40 health systems, including over 100 member hospitals that participate in the 340B Drug Pricing Program (340B program), the Illinois Health and Hospital Association (IHA) appreciates the opportunity to comment on this bipartisan request for information (RFI) on the draft SUSTAIN Act.

Consistent with Congress' intent, Illinois' 340B hospitals have stretched scarce federal resources attained through 340B program savings to provide direct access to healthcare services and medicines for underserved patients, and to support a variety of initiatives that increase access to healthcare services in their communities. However, the 340B program has faced numerous setbacks over the past several years, with the most recent issue beginning in 2020 when pharmaceutical companies began limiting the distribution of drugs acquired
through the 340B program via contract pharmacies.

The myriad legal challenges and differing interpretations clearly demonstrate the need for Congress to provide clarity around programmatic intent and requirements. The 340B program is not a medication access program; rather, it is designed to support

covered entities in their ability to care for low-income, underinsured patients as well as the covered entity's community. The program was intentionally designed to allow covered entities flexibility in how they use 340B savings to care for patients, allowing each provider to assess and meet the unique needs of their patients.

IHA welcomes the opportunity to work with you, Senators, to ensure that the 340B program continues to benefit patients and communities, while preventing any policies that would diminish the scope of the program and jeopardize patient access to care. Our full comments follow.

Sense of Congress

IHA supports the codification of Congress' intent in creating the 340B program: to stretch scarce Federal resources and help safety net providers maintain, improve, and expand patient access to health care services by requiring drug manufacturers, as a condition of participation in the Medicaid and Medicare programs, to provide discounts to covered entities that serve a disproportionate share of low-income and underserved patients. Clearly stating Congress' intent in law will avoid future speculation on the goal of the program as the healthcare landscape continues to evolve.

Contract Pharmacy

IHA appreciates the language in the draft SUSTAIN Act clarifying the ability of covered entities to contract with pharmacies to dispense covered outpatient 340B drugs purchased by the covered entity. However, imposing additional restrictions on the number, location, or type of pharmacy a 340B entity can contract with is counter to Congress' stated intent in creating the 340B program. In fact, Illinois 340B hospitals have experienced the negative consequences of this type of restriction, with one major healthcare system, Ascension, reporting that pharmaceutical companies have forced their hospitals to select only one contract pharmacy within a 40-mile radius of their 340B hospitals. Unfortunately for Ascension's patients, many specialty medications are only dispensed at certain pharmacies located more than 40 miles away from the hospitals providing their care. As a result, Ascension Illinois hospitals have been restricted from helping patients access critically needed specialty medications at affordable prices.

This is just one example of the many reasons covered entities contract with numerous, diverse pharmacies. In Illinois, our academic medical centers and children's hospitals are 340B covered entities, serving patients from every corner of Illinois as well as from neighboring states due to their innovative medical capabilities and breadth of offered services. These hospitals contract with pharmacies in the communities where their patients live in an effort to improve patient access and medication adherence. Limiting the geographic reach of these covered entities would undoubtedly create access issues for their patients. In fact, restrictions on contract pharmacy arrangements have negatively impacted patients at Sinai Chicago, where only one in ten patients have private health insurance. One Sinai patient lost access to diabetes and weight loss medications at their local pharmacy, resulting in a need for more clinic visits and additional medication. Therefore, we strongly advocate against any limitations on the use of contract pharmacies.

Such limitations are also unnecessary given the protections already built into the 340B program. First, contract pharmacies may only dispense 340B drugs to patients of record with the associated covered entity. Second, contract pharmacies are already required to register with the Health Resources and Services Administration (HRSA) and be listed as active on the 340B OPAIS prior to dispensing 340B drugs on a covered entity's behalf. Finally, covered entities are currently responsible for ensuring contract pharmacies are compliant with all 340B program requirements. These guardrails require extra scrutiny of contract pharmacy arrangements on the part of the covered entity, and inherently limit the number of pharmacies a covered entity contracts with.

Additionally, as alluded to in the RFI, many 340B-acquired drugs are only available at select specialty pharmacies. Many times, such pharmacies fill prescriptions through mail orders, making it particularly important that no geographic boundaries are put on a covered entity's ability to contract with the pharmacies necessary to provide the treatments and medications their patients require for optimal health. This is an issue that is not only true for rural covered entities, but for urban safety net covered entities as well.

We also ask Congress to consider directing HRSA to require pharmaceutical manufacturers to pass through lost savings from

the past four years when the utilization of contract pharmacies has been restricted. Increasingly prevalent restrictions have resulted in mounting financial losses for covered entities, threatening service lines and curtailing many of the programs 340B covered entities have historically provided to their communities. Franciscan Health Olympia Fields, for example, has used 340B savings to fund its outpatient infusion center providing comprehensive cancer care; Medication to Bedside program bridging the gap from inpatient to community and ensuring medication access to all patients prior to discharge; and its pharmacy patient assistance program that helps uninsured and under-insured patients obtain necessary medications. All of these programs are at risk as the actions of pharmaceutical manufacturers are adding to the financial challenges facing the health system. Thus, we would ask not only for the codification of covered entities' right to contract with pharmacies, but also for the reconciliation of lost savings resulting from the actions of pharmaceutical manufacturers since 2020.

Patient Definition

IHA appreciates the need for clarity around the definition of a patient in the context of the 340B program. We agree that codification of a definition will be helpful in both providing clarity for covered entities and manufacturers, and in avoiding additional future legal questions in this space. Given the proposal to remain consistent with Congress' intent in creating the 340B program, we believe it is most appropriate to remain consistent and also codify the longstanding definition of patient created by HRSA in 1996.

Current regulation considers an individual as a "patient" of a hospital covered entity if (1) the covered entity has established a relationship with the individual (i.e. maintains records of the individual's healthcare); and (2) the individual receives healthcare services from a healthcare professional who is either employed by the covered entity or provides healthcare under contractual or other arrangements (e.g. referral or consultation) such that responsibility for the care provided remains with the covered entity. An individual will not be considered a ''patient'' of the covered entity for purposes of 340B if the only healthcare service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration at home.

While the 340B program has evolved since its inception, the definition of a 340B covered entity patient operationalized by HRSA has remained clear and relevant. The 340B program focuses on the price of outpatient drugs, not the severity of the illness necessitating the drugs. There is no evidence that Congress intended for 340B-acquired drugs to only be dispensed to patients involved with certain patient encounters or certain levels of service. Nor is there evidence that Congress intended for a meaningful relationship to be dependent on the length of the patient-covered entity relationship.

Rather, if Congress' intent in establishing the 340B program aligns with the stated intent in Section 2 of the draft SUSTAIN Act, to stretch scarce federal resources, then the current definition of patient is more than sufficient. It requires the covered entity to maintain a healthcare record of the patient, and does not allow a relationship to be established by simply the dispensing of drugs. Further, it allows the patient to determine which provider relationships they deem meaningful. Any restrictions on the definition of patient would not only result in restrictions on the program, but may also impede patient access to the care they want from the provider they wish to work with.

Additionally, we have logistical concerns regarding the assignment of savings for patients served by multiple 340B covered entities. We would encourage the Congress to work closely with HRSA and a variety of stakeholders in designing the process for determining and overseeing the distribution of 340B savings. It is our opinion that the covered entity closest to patient care and most likely to shoulder unpaid costs should receive the 340B transaction and related savings.

Child Sites

As the healthcare delivery system shifts toward outpatient, community-based care, the use of child sites has become more important not only for the delivery of services but for patient access. Both Congress and the U.S. Dept. of Health and Human Services have signaled through legislation and policy that they want the shift toward outpatient care to continue. Thus, we urge the Congress to ensure any policymaking regarding child sites not discourage the shift toward outpatient care.

To that end, we have significant concerns with the proposed extension of a covered entity's financial assistance policy to all child sites. In particular, child sites often receive foundation funding, engage in medication-specific financial assistance

programs, or work with patients on a case-by-case basis to ensure healthcare is affordable. Requiring the extension of the covered entity's, or hospital's, financial assistance policy to child sites might impact the ability to engage with these existing funding and discount policies. This could have the unintended consequence of hindering patient access to services and medications, which we believe is counter to the intent of this particular proposal.

Additionally, the current requirement for child sites to appear as a reimbursable line on a hospital's Medicare Cost Report before they are eligible for 340B pricing is administratively onerous, resulting in financial losses for covered entities. We would encourage the Congress to instead codify policy similar to what was permissible during the COVID-19 Public Health Emergency, allowing for 340B pricing at child sites as soon as a patient is recognized as a patient of record with the 340B covered entity. Doing so will ultimately increase access to healthcare for low-income and uninsured individuals.

Transparency

IHA and Illinois' 340B hospitals agree that transparency is important to maintaining the integrity of the 340B program. In fact, Illinois 340B hospitals have embraced the American Hospital Association's 340B Good Stewardship Principles, communicating the value of the 340B program, disclosing estimated savings, and committing to conducting internal reviews to ensure they are meeting HRSA's program rules and guidance.

That said, the proposed Medicare Cost Report addendum would impose administratively burdensome requirements on 340B hospitals and other covered entities without providing meaningful information to policymakers and the public on the true value of the 340B program. Additionally, the proposed transparency requirements would exacerbate a disparity that already exists under the 340B program. Specifically, HRSA audits 200 covered entities each year, but just five pharmaceutical manufacturers. To truly increase transparency in the 340B program, for-profit participants including pharmaceutical manufacturers should be subject to the same level of scrutiny as not-for-profit program participants.

Additionally, much of the proposed transparency requirements are either duplicative, unrelated to the Congressional intent of the 340B program, or logistically difficult to fulfill. For example, patient demographics, a list of contract pharmacies, and the number of individuals who were dispensed or administered 340B-acquired drugs are data points available through existing reporting requirements or the analysis of claims data. The proposed requirements for hospitals to report policies to promote medication adherence and access is unrelated to the intent of the program. And reporting charity care costs by child site location is not only logistically burdensome, but counter to the proposal that child sites be clinically and financially integrated with the covered entity.

Moreover, the proposed methodology for calculating 340B savings of wholesale acquisition cost minus average acquisition cost would result in an overestimate of 340B savings. Requiring this methodology will further inaccurate claims that 340B covered entities are amassing more in savings than they spend on charity care, for example, a claim pushed by the pharmaceutical industry to misrepresent the actions of 340B hospitals.

Finally, requiring this information to be made available across 340B outpatient locations will force 340B hospitals to establish and support a variety of data reporting systems that will undoubtedly be resource intensive. Pharmaceutical companies are already imposing barriers to drug savings through claims share and data reporting requirements, with Southern Illinois Healthcare reporting constraints that amount to over $2 million annually which could have gone to patients and resulting in medication adherence issues impacting the cost of care. This exacerbates the financial challenges 340B covered entities already face due to the reimbursement typically provided for the patient populations they serve. Requiring such detailed data reporting will not only diminish the savings covered entities achieve through participation in the 340B program, but may also pull resources away from other areas of the covered entity as well, such as service lines or payroll.

Enhancing Program Integrity

IHA and Illinois' 340B hospitals agree that the 340B program must be properly administered and overseen. In fact, covered entities are already subject to audit by both the manufacturer and the federal government, while manufacturers are subject to audit by HRSA. It is our presumption that these audits are already conducted in accordance with generally accepted government auditing standards, as is typical practice with government audits. If they are not, then we agree that complying with

such standards is not only appropriate, but will provide consistency in audit procedures across the myriad audits hospitals and other entities are regularly subject to.

While well-intended, requiring covered entities to be responsible for ensuring vendors agree to submit data to the Secretary and independent outside auditors, as well as respond to requests from auditors in a timely manner, seems misplaced. While we agree with the spirit of this proposal, it is unreasonable to hold covered entities accountable for the oversight and practices of vendors. Rather, the government should be ultimately responsible for ensuring vendors are submitting data and responding to requests from auditors. As the recipients of this information, HHS is best positioned to monitor compliance. Should a vendor fail to submit data or respond to an audit request, it would seem the vendor would need to submit a corrective action plan, not the covered entity as proposed. Covered entities should not be threatened with removal from the 340B program due to the actions of pharmacies that are outside the business and control of the entity.

User Fee Program

IHA strongly opposes the implementation of a user fee on 340B covered entities. The purpose of the 340B program is to stretch scarce federal resources for providers that serve a disproportionate number of low-income, underinsured and uninsured individuals. These are the same providers that have high proportions of Medicare and Medicaid enrollees, two patient groups for which hospitals are paid below the cost of providing care. It seems counter to Congress' intent in establishing the 340B program to charge covered entities for participating in a program meant to assist them in enhancing the services they provide to their patients and communities.

In fact, many Illinois 340B hospitals rely on 340B savings to maintain patient access to healthcare services. For example, Sparta Community Hospital has used 340B savings to hire five additional full-time clinicians and several part-time specialty providers for its Rural Health Clinics since 2013, resulting in a 21% increase in patient visits between 2013 and 2023. However, since 2020, Sparta's realized savings from the 340B program have dropped 80% due to restrictions placed on the dispensing of 340Bacquired drugs through contract pharmacies. This year hospital leaders project only $260,000 in drug cost savings, jeopardizing the gains they have made to improve access in their rural community where 12% of residents live in poverty. While a 0.01% user fee seems like a small percentage, taking an additional $2,600 away from this Critical Access Hospital would further exacerbate the precarious financial situation they are in due to the actions of pharmaceutical manufacturers. Further, charging covered entities to participate in a program predicated on the idea of stretching already scarce federal resources seems counter to Congressional intent, and certainly will not help such providers in expanding services and resources to our country's underserved patients and communities.

Thank you again for the opportunity to share our comments with you and your colleagues on the draft SUSTAIN Act. IHA looks forward to working with you to ensure that the 340B program continues to provide access to necessary drugs and services for patients in the communities our 340B hospitals serve. Please direct questions here.

Sincerely,

A.J. Wilhelmi
President & CEO
Illinois Health and Hospital Association