Kentucky Hospital Association

Representing Kentucky Hospitals and Health Systems

March 29, 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 L. Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Submitted via email to Bipartisan340BRFI@email.senate.gov

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

The Kentucky Hospital Association (KHA) represents all hospitals and health systems in the Commonwealth of Kentucky. On behalf of our members, KHA appreciates the opportunity to provide feedback relating to the bipartisan discussion draft titled Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act, or SUSTAIN 340B Act. As we stated in our previously submitted response to the Congressional Bipartisan Request for Information, **the 340B program has successfully allowed health care providers to stretch scarce federal resources to better serve patients and communities and to support essential services, consistent with Congressional objectives, since the program began over 30 years ago.** We appreciate the time you and your colleagues are investing in researching and considering changes to this very important program.

In our July 28, 2023, response to the Congressional Bipartisan Request for Information, KHA provided multiple examples of how our Kentucky hospitals and health systems use the 340B program. The savings 340B hospitals achieve through purchasing certain outpatient drugs at a discount allow them to provide a range of programs and services that directly benefit their patients. General examples include services like medication therapy management, diabetes education and counseling, behavioral health services, opioid treatment services, and the provision of free or discounted drugs. The savings generated from the 340B program go directly back into serving the needs of our communities, our state, our citizens. The 340B program is vital to continue serving and assisting patients throughout our Commonwealth.

KHA appreciates the opportunity to provide feedback on the SUSTAIN 340B draft and appreciates your continued interest in preserving and protecting the 340B program. We hope that Congress takes steps to ensure that the 340B program continues to benefit patients and communities, while avoiding any cuts to the program as any cuts would jeopardize patient access to care.

Here are our specific responses and feedback for each section of the discussion draft.

Sense of Congress

KHA supports the direct statement of Congressional intent included in *Section 2, Sense of Congress*. The 340B program was established by Congress in 1992 "to stretch scarce (rather than "scare" as stated in the draft) Federal resources and help safety net providers maintain, improve, and expand patient access to health care services." The 340B program requires, as a condition of participation in Medicare Part B and Medicaid, that drug manufacturers "provide discounts to covered entities that serve a disproportionate share of low-income and underserved patients."

Contract Pharmacy

Under *Section 3, Contract Pharmacy,* the draft recognizes contract pharmacies as an essential component of the 340B program and prohibits drug companies from restricting access to 340B drugs through contract pharmacies through two listed prohibitions (see Sec. 3(a)(11)(A)(iii)(I) and (II)) and one general prohibition (see Sec. 3(a)(11)(A)(iii)(III)). This last open-ended provision could be problematic. KHA suggests that the draft be amended to include language specifically prohibiting drug companies from imposing any restrictions or conditions on 340B drugs rather than leaving open the possibility of a future loophole.

As noted in the Explanatory Statement, "due to a lack of statutory clarity, there has been ambiguity over the use of contract pharmacy arrangements which has led to litigation." KHA applauds your desire to provide statutory clarity to ensure patient access, while enhancing program integrity and accountability. The need for statutory clarity is evident in the growing number of states, including Kentucky, that have considered legislation protecting contract pharmacies against discrimination. For example, 2024 Kentucky Senate Bill 27 would prohibit a manufacturer from discriminating, or causing "others to discriminate, against a 340B covered entity by refusing or withholding 340B pricing for a covered drug if the manufacturer offers the same drug at a 340B price in any other state." The bill specifies that discrimination "includes but is not limited to any manufacturer-imposed condition, limitation, or delay on the sale of or purchase of a covered drug at a 340B price, unless the condition, limitation, or delay is expressly required under federal or state law, or can be proven to be beyond the control of the manufacturer." (Link: https://apps.legislature.ky.gov/recorddocuments/bill/24RS/sb27/bill.pdf)

Under "(B)", each covered entity would be required to annually register with the Secretary of Health and Human Services each of their contract pharmacy arrangements, including for each parent and child or associated sites, and attest to compliance with applicable rules. The draft also requires that each written contract be submitted to the Secretary. However, hospitals are already required to register each contract pharmacy arrangement with the Health Resources and Services

Administration (HRSA). Rather than requiring annual registration for all contract pharmacies, the bill should require registration only of new contract pharmacies. Additionally, each covered entity, which would include all of its child sites, is the legal entity entering into the contracts with a pharmacy so requiring hospitals to register each contract pharmacy arrangement with the parent, child, and associated sites is unnecessary and overly burdensome.

Under "(C)", the Secretary will establish a process to review all written agreements between covered entities and each contract pharmacy. KHA is concerned this requirement could lead to a delay in patient access and services while waiting for HRSA to complete the contract reviews and also could result in the disclosure of sensitive business information. Lastly, the time and resources that will be spent on compliance with this requirement takes away time and resources better allocated to patient care.

The Supplemental Request for Information asked several questions regarding the use of contract pharmacies. In response to those questions, KHA supports codification of the intent of 340B to generate savings for safetynet providers to expand access, not to go to the patient, and KHA supports codification of the ability of covered entities to use contract pharmacies.

KHA recognizes that contract pharmacies are an important access point for patient care, for both urban and rural, and locations near or far from the hospital. Depending on the needs and location of their patients, hospitals are in the best position to know whether local, specialty, mail-order, or a combination of pharmacies are needed to best serve their patients. Hospitals should not be restricted in their use of contract pharmacies based on geographic or other limitations. If a geographic limitation is needed, KHA would ask that the geographic area align with the service area of the covered entity, including the ability to cross state lines as Kentucky is bordered by seven (7) states. Any limitation should not just be the primary service area, since regional hospitals and urban centers are tertiary centers and possibly have a statewide and multi-state service area.

Additionally, hospitals should not be subjected to white bagging restrictions or requirements. Specialty drugs, often at the center of white bagging requirements, are used to treat chronic and complex medical conditions and usually require special handling and close monitoring and adjustments by physicians. Those restrictions interfere with the provider's ability to adjust dosages to patient needs and reactions. Lastly, KHA recommends limiting the role and influence of pharmacy benefit managers (PBMs) in the 340B program and suggests an approach similar to that of 2020 Kentucky Senate Bill 50, which has been considered model legislation for reforming PBMs. (Link - https://apps.legislature.ky.gov/recorddocuments/bill/20RS/sb50/bill.pdf)

Patient Definition

The Explanatory Statement noted that recent litigation raised questions about the previously proposed definition of "patient" and suggested that Congress provide a clear definition of "patient" in the 340B statute. However, HRSA guidance from 1996 has provided an easy test to determine if an individual is a 340B-eligible patient: does the patient have an established health care relationship with the 340B covered entity and is that relationship documented in the patient's health care records? This existing definition has made program oversight easier as hospitals and health systems have had the necessary compliance programs and systems already in place to adhere

to that definition. Thus, KHA would first recommend keeping the HRSA guidance definition rather than amending or codifying that definition. We do not want a restrictive patient definition.

However, KHA also recognizes that the Current Procedural Terminology (CPT) defines "new patient" to mean an individual who has not received any professional services from the physician or that physician's practice within the past three years. Similarly, the CPT codes define an established patient as an individual who has received professional services from the physician or practice within the past three years. The 1996 HRSA patient definition could be modified to require the individual to have received professional services from the covered entity within the past three years as documented within the patient's health record.

If an individual can be identified as a qualified patient of multiple 340B covered entities, the covered entity that prescribed the specific prescription at issue should be considered the 340B covered entity for that prescription. For instance, if a patient receives ongoing treatment at Hospital A for a specified and ongoing medical condition but is treated at Hospital B for an emergency situation, coverage for prescriptions stemming from the emergency situation would be credited to Hospital B as the 340B covered entity, while that patient's ongoing prescriptions for the medical condition would continue to quality Hospital A as the 340B covered entity,

Child Sites

The Explanatory Statement states that "Stakeholders have expressed concerns about the lack of clarity in the establishment and use of child sites in the 340B program…We believe it is important to the integrity of the program that child sites are wholly-owned by and financially and clinically integrated into the covered entity." KHA disagrees with that statement, especially as it fails to consider how the shift from inpatient hospital care to outpatient hospital care has significantly improved patient access to health care overall. Consistent with the goals stated in Section 2 for the 340B program, outpatient facilities expand access to 340B hospital services based on the specific needs of each community by providing a broad range of care or a single service.

While the number and location of child sites might be a concern for drug companies, in reality, those child sites – or outpatient departments, clinics, or offsite facilities – help meet patient demand and expand access to outpatient care. The prescription origination language should be removed as individuals should be considered patients of the 340B program's contract entity, not a specific provider. There should not be additional restrictions on the use of child sites. Such restrictions would serve only to reduce access to care and negatively reduce the value of the 340B program to patients.

Requiring that 340B child sites be wholly-owned would exclude those sites that are recognized under 42 C.F.R. 413.65(f) as joint ventures between rural hospitals and other hospitals or health systems. That restriction undermines the 340B program and will reduce access to care, especially in our rural areas.

The proposed registration requirements for 340B hospitals are burdensome and unnecessary. Section 5(12)(A)(i) requires that each child site be registered with the Secretary. However, hospitals are already required to submit documentation to the Centers for Medicare and Medicaid

Services for provider-based status for child sites. This HRSA registration as a 340B child site would be duplicative and burdensome.

KHA also recommends that current child sites be grandfathered in as eligible and we caution against tracing the child site's use of 340B savings rather than the parent site's use. Hospital and health system leaders make decisions daily to use ***all*** of their facilities and providers to meet the health care needs of their communities. As such, child sites are extensions of the parent (or main) hospital. They are clinically and financially integrated – and should be treated that way in the 340B program. It is imperative that 340B savings reside with the parent hospital, not each child site, so that the parent hospital can use the 340B savings to meet its community's needs, looking at all of its facilities and services.

Transparency

Transparency measures should only be implemented if the measures are meaningful, accurate, and reduce unnecessary burdens. They should not merely provide fodder for program opponents who might misuse that information to lobby for cuts or reductions in the 340B program. For each requested piece of information, KHA recommends asking if that data or information already exists. If a 340B hospital is already reporting a requested type of information on a required cost report, IRS 990 form, or other document, is the duplication really necessary?

The draft bill focuses on charity care as an important aspect of transparency. While charity care is one possible important benefit of the 340B savings achieved by hospitals, charity care by itself does not include other important benefits, such as behavioral health treatment or medication management services. KHA requests changes to the charity care provisions to request information at the covered entity level (the parent site) rather than at the child site or contract pharmacy levels.

It's also important to ensure that any transparency requirements define 340B savings consistently using the same formula the hospitals use. Currently, Section 6(5)(A)(x) of the draft bill defines 340B savings as the difference between a drug's wholesale acquisition cost and the 340B acquisition price, but that definition varies from how hospitals and health systems define 340B savings. The latter estimates 340B savings as the difference between the price paid for the drug under the 340B program and the price it would have paid without the program (which would be the group purchasing organization's price not the wholesale acquisition cost).

Transparency requirements go hand-in-hand with maintaining program integrity. However, this draft does not include any transparency requirements for drug companies or manufacturers. While many 340B hospitals voluntarily share information about 340B savings and how those savings are used, the public does not receive information about how drug companies set or increase prices or how they make decisions relating to pricing or restrictions. It would be helpful to know what considerations lead to drug companies' pricing decisions and how providers and patients can mitigate arbitrary and exorbitant price increases for medications necessary for lifesaving or life-sustaining purposes.

Enhancing Program Integrity

KHA believes that HRSA's current auditing measures are sufficient for ensuring program integrity and there is not a need to expand HRSA's audit authority or to create additional oversight. If independent pharmacies became subject to government audits, changes would be necessary in existing contract terms between hospitals and contract pharmacies, and some independent pharmacies might decide not to contract with a 340B hospital because of that. Congress is tasked with oversight of 340B hospitals and should not expand that authorization to include contract pharmacies.

Currently, a covered entity may be removed from the program for audit violations that are both "knowing and intentional" and "systematic and egregious." However, that standard is not included in the bill draft, which is concerning as a single violation could result in an expulsion from the program, regardless of the reason. Additionally, we recommend that the timeline for implementing a corrective action plan be extended from six months to one year, to allow for annual contracts that may be necessary.

The proposed program integrity requirements are focused solely on expanding program integrity measures and the scope of audits for hospitals and other covered entities, without any additional requirements on drug companies. The same audit requirements should be established for all stakeholders, including drug companies and manufacturers. Lastly, while drug companies are able, in coordination with HRSA, to audit 340B hospitals, surprisingly the reverse is not true. Hospitals and other covered entities should also be able to audit drug companies. Congress should hold drug companies to the same level of accountability as it holds hospitals and covered entities.

Preventing Duplicate Discounts

In order to prevent duplicate discounts between the 340B program and Medicaid, the draft proposes to create a national third-party clearinghouse. However, it is not clear why Section 8 amends the Social Security Act rather than the Public Health Service Act, and whether HRSA or CMS would oversee the clearinghouse and its data collection? Given the placement of this data collection authorization under the Social Security Act, rather than the Public Health Service Act, protections are needed to limit the use of this data to the original scope of preventing duplicate discounts. It's also crucial to note that mitigating duplicate discounts should not require collecting claims data from all payers and this data should not be shared with drug companies. KHA is adamantly opposed to the creation of an all-payer claims database and to the potential sharing of that data with drug companies.

Ensuring the Equitable Treatment of Covered Entities and Pharmacies Participating in the 340B Drug Discount Program

KHA strongly supports the draft bill's provisions in Section 9 to prohibit pharmacy benefit managers and insurers from engaging in discriminatory 340B pricing and patient steering tactics. Not only do those discriminatory pricing and patient steering tactics undermine the 340B program, they threaten patient access to drugs and highlight the out-of-control nature of PBMs in regard to access to outpatient prescription drugs for patients. Establishing these anti-discrimination

provisions at the federal level will provide the same protections to all hospitals and contract pharmacies, without reliance on the state in which the entity is located.

User Fee Program

Section 10 establishes a user fee to be paid by covered entities in order to participate in the 340B program. The establishment of a fee, regardless of its amount, would divert funds away from the patient populations the program is designed to serve. Section 2 clearly stated that the 340B program is designed to provide financial resources to covered entities to provide critical patient services in order to "maintain, improve, and expand access to care." KHA opposes any user fees and requests deletion of this section.

Definitions (Eligibility for the 340B Program)

Currently, Section 13 adds a definition of "child site" and "contract pharmacy" to 42 U.S.C. 256b. KHA proposes that the definition of "covered entity" included in that same statute also be amended to allow all hospitals that meet the eligibility criteria to participate, whether they are nonprofit or for profit. Many of Kentucky's proprietary hospitals are critical access facilities, Medicare sole community and rural referral center hospitals, and they meet the Medicare disproportionate share criteria required to participate in the 340B program. However, they are precluded from 340B participation solely based on their ownership status. The 340B proprietary exclusion is harming the viability of our hospitals, including some hospitals that lost 340B savings when their ownership status changed. The 340B program should allow investor-owned hospitals and all rural hospitals to reduce the price of expensive outpatient pharmaceutical medication for patients. Additionally, KHA supports grandfathering hospitals into the 340B program if the hospital has merged or been acquired by an investor-owned hospital or system.

When a nonprofit rural hospital is acquired by a for profit organization, the rural hospital does not automatically become profitable. KHA has examples of rural hospitals in our state that continue to struggle, and their financial difficulties are compounded because those hospitals lost their ability to continue to participate in the 340B program solely due to their ownership status change. These hospitals continue to serve disadvantaged patients, yet now lack the ability to obtain reduced price medications. The intent of the 340B program is to allow safetynet providers to stretch scarce resources by using savings on the purchase of outpatient medications to expand access to care. This goal applies equally to nonprofit and for profit hospitals. Both types of hospitals are safetynet providers in rural areas, as the sole provider in most Kentucky counties to vulnerable patients. These hospitals should have the ability to purchase lower priced drugs, which would enable them to assist their communities by supporting additional services, such as Hep C clinics, cancer treatment, and helping their patients receive free or reduced cost medication. Kentucky hospitals that participate in 340B are already providing transparency on how they use the savings from 340B, which would be no different if for profit hospitals were able to benefit from the purchase of discounted medications.

Effective Date

KHA recommends that the effective date for this bill, which is included in Section 14, be changed to at least one year from the date of its enactment to give adequate time to all stakeholders to make the necessary changes.

In conclusion, KHA appreciates the opportunity to share our comments with you regarding the SUSTAIN 340B draft. If you would like additional information about the 340B program in Kentucky, please contact Donna Little, KHA's Associate Vice President of Health Policy and Regulatory Affairs, by email at dlittle@kyha.com or by telephone at (502) 992-4378.

Sincerely,

Nancy Galvagni
President