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Advancing Health in America

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October 27, 2026

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

The Honorable Tammy Baldwin
United States Senate
709 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 Tim Kaine
United States Senate
231 Russell Senate Office Building
Washington, DC 20510

The Honorable John Boozman
United States Senate
555 Dirksen Senate Office Building
Washington, DC 20510

The Honorable John Hickenlooper
United States Senate
374 Russell Senate Office Building
Washington, DC 20510

Re: Comments on the SUSTAIN 340B Act (S. 5244)

Dear Senators Moran, Baldwin, Capito, Kaine, Boozman and Hickenlooper:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to provide feedback on the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN 340B Act). Thank you for your bipartisan leadership and sustained commitment to protecting and strengthening this vital program. We share your goals of ensuring greater clarity, accountability and long-term stability for the patients and communities that rely on the 340B program.

For more than 30 years, the 340B program has helped eligible hospitals lower drug costs while enabling them to stretch limited resources to maintain, improve and expand access to care and a range of support services for the nation's low-income, uninsured, rural and medically complex patients and communities. This is particularly important as hospitals' drug costs continue to rise rapidly, growing by 13.6% in 2025 alone — the fastest growing expense category for hospitals.[1] Notably, the benefits of the 340B

[1] https://www.aha.org/system/files/media/file/2026/03/Costs-of-Caring-2026.pdf

program are not generated through any taxpayer appropriations. Instead, participating drug manufacturers provide upfront discounts to eligible hospitals, allowing these entities to reinvest savings to address the unique needs of the communities they serve. However, the 340B program does not only benefit eligible hospitals and their patients. In exchange for providing these discounts, drug manufacturers get access to two of the largest markets for their drugs — Medicare and Medicaid — allowing them to generate billions of dollars in taxpayer-funded sales.

The 340B program is meeting the goals Congress set when it established the program in 1992. For example, recent data show that 340B hospitals provided nearly $100 billion in community benefits in a single year. However, we recognize the need to ensure the program is continuing to meet its mission and appreciate efforts to strengthen the integrity of the program, particularly as drug manufacturers have repeatedly tried to undermine its purpose.

The SUSTAIN 340B Act represents a constructive bipartisan effort to establish clear and durable rules for all stakeholders in the program. We particularly appreciate your efforts to codify the program's purpose; protect the upfront 340B discount by ending the 340B rebate model or any such future program; protect hospitals' use of contract pharmacies; establish a neutral clearinghouse to facilitate data exchange and promote program integrity; prohibit discriminatory practices by health plans and pharmacy benefit managers (PBMs); and provide additional resources to ensure oversight remains strictly with the federal government. These provisions would address many of the significant challenges facing 340B hospitals and provide needed stability for the program. However, as you continue to gather input to strengthen this bill, we respectfully ask you to reconsider several provisions so that they are workable for 340B hospitals of all sizes and do not unintentionally reduce patient access to medications or essential healthcare services. Below, we provide our detailed feedback on certain aspects of the bill.

CODIFYING THE PURPOSE OF THE 340B PROGRAM

We strongly support the bill's provision to codify in statute that the purpose of the 340B program is to "stretch scarce federal resources and help safety-net providers to maintain, improve and expand patient access to healthcare services […]." As you know, program critics have attempted to create their own definitions, narrowing the program's purpose to fit their self-interested needs. 340B hospitals around the country understand the purpose of the program is to provide them with additional resources to support their efforts to ensure the communities they serve can have access to the healthcare services they need. We commend your willingness to define this purpose in statute and provide certainty to all stakeholders about Congress' intent.

In addition, we appreciate your inclusion of language that codifies the 340B discount as an upfront discount at the point of purchase. This will further define Congress' intent of the mechanism by which 340B discounts should be offered to eligible 340B entities and

thereby ensure that policies intended to impose alternative discount mechanisms, such as the 340B rebate model, are not pursued further.

PROTECT THE UPFRONT DISCOUNT AND ESTABLISH A CLEARINGHOUSE

We strongly support the bill's provisions ending the 340B rebate model and preserving the upfront 340B discount. Congress structured the 340B program to provide eligible hospitals with discounted prices at the point of sale, and that has provided predictable and enforceable pricing for decades. Upfront discounts allow hospitals to manage cash flow, plan pharmacy budgets and sustain the medications, services and community programs supported by 340B savings.

Under a rebate model, hospitals must pay the full price for outpatient drugs, submit extensive claims data and wait for manufacturers to determine whether, when and in what amount a rebate will be paid. This approach shifts financial risk to hospitals, creates substantial administrative burdens and gives manufacturers greater control over access to discounts required under the program. These burdens would be especially challenging for rural, and financially vulnerable hospitals and could divert resources away from patient care to managing an array of unnecessary and burdensome administrative processes.

The AHA also strongly supports the bill's establishment of a national, neutral third-party clearinghouse. A properly designed clearinghouse is the right approach to strengthening program integrity because it can facilitate necessary data exchange, strengthen program integrity standards, and verify pricing and eligibility without transferring oversight control of the 340B program to manufacturers or disrupting hospitals' access to upfront discounts.

Unlike the unilateral manufacturer data policies or a retrospective rebate model, a neutral clearinghouse would provide a single, standardized and federally supervised process for all stakeholders. This would avoid requiring hospitals to navigate multiple manufacturer-specific platforms and policies, data formats and compliance systems, which would create unnecessary costs and administrative complexity. It also would provide greater consistency and accountability by ensuring that program integrity determinations are governed by uniform federal standards rather than ever-changing policies set by each drug manufacturer.

PRESERVE CONTRACT PHARMACY ACCESS

The AHA strongly supports the bill's recognition of contract pharmacies as an integral part of the 340B program and its prohibition on manufacturer-imposed numerical, geographic, and data submission restrictions on their use. Contract pharmacies serve as an extension of the 340B hospital, allowing patients to obtain their prescribed medications through the convenience of their local community pharmacies and access

specialty or limited-distribution drugs that may not be available through a hospital's own pharmacy.

Many 340B hospitals, particularly rural hospitals, do not operate their own pharmacies because of the significant investment required to establish and operate a pharmacy. Thus, many 340B hospitals rely on a network of contract pharmacies both to derive benefit from their participation in the 340B program and to ensure their patients can access their prescribed medications. Indeed, data show that 80% of rural 340B hospitals have at least one contract pharmacy relationship.[2] Moreover, 340B hospitals are more likely to contract with pharmacies in areas of high need. For example, 340B hospitals have contracted with local pharmacies in 70% of U.S. counties reporting poor health, 73% of counties reporting high diabetes prevalence, and 82% of counties reporting high food insecurity.[3] Therefore, we appreciate your recognition of the need to maintain flexible access to local, specialty and mail-order pharmacies that will help reduce transportation barriers, support continuity of care and allow hospitals to tailor pharmacy networks to their patients' needs.

However, we are concerned with the provision in this section that permits manufacturers to directly audit the contract pharmacies themselves. While we recognize the need to ensure compliance with all 340B rules and regulations, this authority should be limited to the federal government and not extended to manufacturers. Many pharmacies, both large chains and small independent pharmacies, may refuse to open themselves up to audit by drug manufacturers and, therefore, may be unwilling to participate in 340B contract pharmacy arrangements altogether. This fear is not merely theoretical. We have seen several pharmacies choose to exit the 340B program either entirely or for certain drugs due to increasing administrative burden.[4] If contract pharmacies choose not to participate, then it would undermine the very purpose of codifying the use of contract pharmacies in the 340B program. Accordingly, we urge you to reconsider this provision.

ESTABLISH A DURABLE PATIENT DEFINITION

The current patient definition standard established through the Health Resources and Services Administration (HRSA) guidance provides a sufficient standard to ensure that only patients of the 340B hospital are receiving 340B drugs. This standard has been in place since 1996 and, most importantly, has provided the necessary flexibility for 340B hospitals to adapt to modern care delivery mechanisms such as telemedicine. While HRSA's current standard is working well, we also understand the interest of Congress in

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[2] https://www.aha.org/system/files/media/file/2024/09/Ensuring-Access-to-Care-340B-Arrangements-with-Community-and-Specialty-Pharmacies-Improve-Access-to-Care.pdf

[3] *Ibid*.

[4] https://www.340bpriceguide.net/articles-news/147-walgreens-to-temporarily-stop-340b-discounts-at-contract-pharmacies-for-certain-expensive-drugs

establishing a clear, consistent and enforceable patient definition standard. However, any definition must be sufficiently durable and flexible to reflect modern care delivery, including referrals, integrated care teams, telehealth, remote monitoring, specialty pharmacy services and continuing treatment of chronic or complex conditions.

A rigid prescription-by-prescription test could exclude legitimate patients whose care continues over time or involves multiple practitioners across the healthcare system. It also could create substantial administrative complexity by requiring hospitals to trace every prescription to a particular encounter, even when the covered entity maintains an ongoing clinical relationship with the patient and remains responsible for coordinating the patient's care. We therefore encourage the sponsors to establish an objective and auditable standard focused on whether the covered entity maintains a meaningful clinical relationship with the patient and responsibility for the patient's care.

We also ask the sponsors to reconsider the categorical exclusion of certain infusion, drug administration and clinician-administered drug encounters. The bill's patient definition provisions generally exclude individuals receiving drug administration services or drug infusions, subject to limited exceptions. When a hospital reviews and prepares the medication, administers it, monitors the patient, responds to complications and bears the drug cost, it has assumed meaningful clinical and financial responsibility for the care. The bill should provide a pathway for these encounters to qualify when appropriate documentation and program integrity safeguards are satisfied.

REMOVE CHILD SITE RESTRICTIONS

Hospital-owned hospital outpatient facilities, commonly referred to as child sites in the 340B program, extend a variety of services such as oncology, behavioral health and maternal care into the communities hospitals serve. They help 340B hospitals sustain local access to these critical services and support other essential patient and community programs.

While the bill preserves currently eligible child sites and establishes ownership, integration, registration and financial-assistance standards for participating sites, it also imposes a three-year delay on newly acquired sites that were not already eligible for 340B discounts. This provision is misguided. In many cases, hospitals acquire outpatient clinics in order to preserve local access to a particular service or set of services. These clinics would otherwise likely close their doors due to poor finances or other complicating factors. Imposing an arbitrary three-year delay disadvantages the communities where these services are needed to be maintained. Thus, any newly acquired child site that satisfies all applicable ownership, integration and operational standards should be allowed to participate in the 340B program without delay. Moreover, withholding eligibility after those requirements are met could limit the resources available across the 340B hospital to integrate, sustain or expand outpatient access in underserved communities. We urge the sponsors to remove or substantially

modify the three-year delay and ensure that child-site eligibility rests on clear, durable and administrable standards.

We also urge the sponsors to reconsider their requirement for child sites to be wholly-owned in order to be eligible for the 340B program. This requirement does not sufficiently account for the range of relationships that can exist in the operation of a child site. While some child sites may be wholly-owned, other child sites are operated as joint ventures, as recognized under the Medicare provider-based guidelines in 42 CFR 413.65(f). This is especially true for some rural hospitals that operate a child site at a facility that is jointly owned by another hospital or health system and staffed by physicians that are either contracted or employed by the 340B hospital. These joint ventures are critical parts of the healthcare system that help ensure healthcare services remain accessible within local communities. Restricting the ability of such joint ventures to be eligible for the 340B program undermines Congress' intent of the program and will sharply reduce access to care, especially in rural communities.

TRANSPARENCY REQUIREMENTS MUST BE MEANINGFUL AND PROPORTIONATE

The AHA supports meaningful transparency that demonstrates how 340B hospitals use program savings to benefit patients and communities in keeping with the congressional purpose of the program. However, we are concerned that some of the requirements that this bill would impose would not be meaningful to evaluate the value of the program and could, instead, mislead Congress, the federal government and the public. Without sufficient standardization and coordination, the new requirements could duplicate existing reporting, require hospitals to reconcile information across multiple internal and external systems, and divert resources from patient care. Reporting also should provide sufficient context to reflect the full range of services supported by 340B savings and protect patient and proprietary information.

The SUSTAIN 340B Act would require covered entities to submit annual reports to the Department of Health and Human Services (HHS) covering the parent entity, child sites and contract pharmacy arrangements. Reporting would include patient and prescription volumes, payer mix, charity care, uses of 340B savings, patient financial demographics, access and adherence policies, government contracts, third-party administrators, Medicare and Medicaid shortfalls, outpatient volume and 340B operating costs. HHS would publish this information in a searchable public format and report annually to Congress. This extensive level of reporting is particularly concerning when 340B hospitals already report an enormous amount of information to the government, much of which is public. Hospitals report related information through Medicare cost reports, IRS Form 990 filings, HRSA's annual recertification process and the public registration of child sites and contract pharmacies. For example, 340B hospitals report charity care, Medicare and Medicaid shortfalls, and uncompensated care, among other metrics, through Form S-10 of the Medicare cost report. In addition, many 340B hospitals

voluntarily report their estimated savings and how those resources support local healthcare needs through AHA's 340B Good Stewardship Principles campaign.

Therefore, we urge the sponsors to make transparency requirements standardized, auditable and proportionate to their oversight value. Transparency measures also should apply across all program stakeholders, including comparable visibility into manufacturer pricing decisions and compliance, as well as payer and PBM practices. This would provide policymakers with a more complete understanding of how the 340B program operates within the broader pharmaceutical landscape and help ensure that program resources remain available for patient care.

MAINTAIN FLEXIBLE PATIENT FINANCIAL ASSISTANCE

The AHA appreciates the bill's focus on helping low-income patients afford their medications and care. Hospitals share the goal of helping patients afford the medications and care they need. The bill would require hospitals to provide financial assistance to patients at or below 200% of the federal poverty level, communicate their policies clearly, and extend them to child sites and contract pharmacies after three years.

340B savings benefit patients in many different ways. These are often tailored to community needs and may not be captured by a single financial-assistance requirement. In addition to direct medication assistance, hospitals use these resources to sustain access to services such as oncology, behavioral health, maternal health, medication-management and transportation. Instead of a uniform federal requirement, we would encourage the bill's sponsors to take a more flexible approach that allows hospitals to tailor assistance to local needs that complement existing hospital policies, state requirements and the broader community-wide mission of 340B.

In addition, a requirement that 340B hospitals provide financial assistance to patients receiving medications through contract pharmacies may be difficult to implement in practice because contract pharmacies are independent entities that often do not know at the time of dispensing whether a prescription will ultimately qualify as a 340B drug. In many contract pharmacy arrangements, 340B eligibility is determined retrospectively through replenishment and claims-matching processes, creating challenges for applying patient-specific discounts at the pharmacy counter. Hospitals also may lack direct control over contract pharmacy point-of-sale systems, making it difficult to consistently verify income eligibility, apply reduced cost-sharing, reimburse pharmacies for forgone revenue, and audit compliance across potentially large networks of retail, specialty and mail-order pharmacies. In addition, implementing a prescription-level financial assistance requirement could necessitate new data-sharing arrangements, operational systems and reconciliation processes among hospitals, pharmacies and third-party administrators, creating significant administrative complexity and compliance burdens.

While 340B hospitals strongly support helping low-income patients afford medications, a rigid contract pharmacy financial assistance mandate may be operationally challenging given the way most 340B contract pharmacy arrangements function today and undermine the very access to care this provision is intended to achieve. Therefore, we urge you to reconsider the requirement to apply financial assistance standards to patients receiving drugs through contract pharmacies. We are happy to continue to work with you to find solutions that achieve the intended goal while accounting for how contract pharmacy arrangements currently operate and providing hospitals with sufficient flexibility to implement the policy effectively.

CONCLUSION

The AHA greatly appreciates your continued bipartisan leadership to strengthen and preserve the 340B program. We remain committed to working with you on our shared goal to maintain this critical program for the hospitals, communities and millions of patients who depend on it. Please contact me directly if you have questions, or have a member of your team contact Aimee Kuhlman, AHA group vice president of advocacy and grassroots, at akuhlman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President