American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

Submitted electronically

September 23, 2026

The Honorable Scott Peters
U.S. House of Representatives
Washington, D.C. 20515

The Honorable John Joyce, M.D.
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Jake Auchincloss
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Dan Crenshaw
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Nanette Barragán
U.S. House of Representatives
Washington, D.C. 20515

Re: Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act (SECURE 340B Act)

Dear Representatives Peters, Joyce, Auchincloss, Crenshaw and Barragán:

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 your bipartisan leadership in introducing the Strengthening the Exercise of Controls and Upgrading Requirements for Efficiency in 340B Act (SECURE 340B Act) and the opportunity to provide feedback on the legislation. While we share your goals of strengthening program integrity, improving accountability and ensuring that patients have access to the medications they need, we are concerned that certain provisions in the bill would not achieve those goals and could instead weaken the ability of 340B hospitals to serve their patients and communities.

For more than 30 years, the 340B program has helped eligible hospitals stretch limited resources to expand access to care and support services for low-income, uninsured, rural and medically complex patients and communities. The program is not a federal spending program and does not rely on taxpayer appropriations. Rather, it requires participating drug companies to provide up-front discounts to eligible covered entities in exchange for having access to one of the largest markets for their drugs — Medicaid and Medicare. These discounts generate critical cost savings that allow hospitals to maintain, improve and expand access to patient care and essential community services.

Hospitals support reasonable, workable reforms that protect the 340B program for the patients and communities it was designed to serve. The AHA appreciates several provisions in the SECURE 340B Act that would strengthen and protect the program, particularly its statutory recognition of contract pharmacy arrangements and its prohibition on health plans, insurers and pharmacy benefit managers (PBMs) discriminating against covered entities or contract pharmacies based on 340B status. These provisions would help curb ongoing efforts by manufacturers and payers to undermine the program. However, several other provisions in the bill would fundamentally alter the operation of the program, impose substantial new administrative and financial burdens on hospitals, and reduce patients' access to medications and essential healthcare services. Our detailed feedback on the bill's provisions follows.

PROTECT THE UPFRONT DISCOUNT MODEL

The bill would require manufacturers to provide the 340B ceiling price as an upfront discount, rather than through a retrospective rebate, for four years while a national claims-level clearinghouse is established. After that period, continued protection of upfront pricing would depend on federal certification that the clearinghouse meets specified performance benchmarks for claims processing, duplicate-discount identification, timely adjudication and data completeness.

We believe that shifting to a retrospective rebate model, even on a contingent basis, would fundamentally alter the structure of the 340B program and create serious risks for hospitals and the patients they serve. Under a rebate approach, hospitals would be required to purchase drugs at full price up front and then wait — potentially for an extended period of time — for manufacturers to process, approve and issue a rebate, creating significant cash-flow strain that would be particularly acute for rural, safety-net and other financially vulnerable hospitals already operating on thin margins. A rebate model also would shift control of the program away from the Health Resources and Services Administration (HRSA) and toward drug manufacturers, giving them greater discretion over whether and when a hospital ultimately receives the discount to which it is entitled by statute, and creating new opportunities for manufacturers to delay, reduce or deny payment based on documentation disputes or technical errors rather than statutory program violations. In effect, under a rebate model, hospitals would be extending drug companies an interest-free loan while continuing to bear the full, unreimbursed cost of acquiring medications for their patients in the interim. The AHA strongly supports the bill's initial prohibition on rebate models and the establishment of a national claims-level clearinghouse but urges the sponsors to permanently bar the rebate model.

SUPPORT CONTRACT PHARMACY PROTECTIONS, STREAMLINE NEW REQUIREMENTS

For many Americans, local pharmacies are a convenient and trusted source of care. In rural communities, where transportation options can be limited, access to a patient's prescribed medication in the convenience of their local pharmacy is vital to ensuring medication adherence and keeping care close to home. When a 340B hospital partners with a local pharmacy it ensures access to medications and continuity of care. Moreover, rural hospitals often lack the resources to operate their own pharmacies, so they rely on a network of contract pharmacies to generate 340B savings and ensure patients have access to care and their medications. Data show that 80% of rural hospitals operate contract pharmacies.[1] Hospitals also have contracted with pharmacies in 82% of U.S. counties with high food insecurity, 77% of counties with the highest diabetes prevalence and 70% of counties that report poor health.[2] These data show 340B hospitals contract with pharmacies that are located in areas of need where ensuring medication adherence and access to care is critical.

The AHA appreciates the bill's recognition of contract pharmacies as a core component of the 340B program. In addition, we appreciate that the bill includes no numerical or geographic limitation on the use of contract pharmacies. This provision is particularly important for patients who live far from a hospital, rely on community pharmacies near their homes or workplaces, require specialty medications or lack reliable transportation.

At the same time, the bill includes several contract pharmacy provisions that would impose new registration, contracting, recordkeeping, reporting, audit and claims-level data obligations. While we recognize your interest in ensuring program integrity, we are concerned that these provisions could be onerous on 340B hospitals and could push some contract pharmacies to exit the program and thereby limit the very access they are intended to protect.

REVISE THE PATIENT DEFINITION

The AHA believes that the current patient definition established through HRSA guidance provides a sufficient standard to ensure program integrity. This standard has been in place since 1996 and has provided the necessary flexibility for 340B hospitals to adapt to modern care delivery mechanisms. While we believe HRSA's current standard is working well, we also understand the interest of Congress in establishing a clear and consistent patient definition. However, we believe that any definition must be durable enough to account for modern care delivery mechanisms, including virtual care, remote monitoring, referrals, integrated care teams and specialty pharmacy services. The bill would require that each prescription be tied to a qualifying outpatient encounter within the preceding 24 months, along with extensive documentation of the provider-patient relationship. While we appreciate the bill's inclusion of a limited referral pathway for

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[1] 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
[2] *Ibid*.

federally qualified health centers, critical access hospitals and sole community hospitals, a rigid, prescription-by-prescription test could exclude legitimate patients whose care continues over time, involves multiple practitioners, or is managed through integrated care teams or virtual care. It also would create significant administrative complexity by requiring hospitals to trace and document each prescription's connection to a qualifying encounter — a particular challenge for patients with chronic or complex conditions whose regimens are adjusted between visits.

We are concerned that codifying an overly rigid definition risks excluding legitimate patients now and could require repeated legislative fixes as care delivery continues to evolve, particularly with the advent of artificial intelligence and other technologies. Therefore, we urge Congress to adopt a durable standard focused on whether the covered entity maintains a meaningful clinical relationship with, and responsibility for, the patient's care, rather than requiring every prescription to be tied to a narrowly defined encounter.

REVISE THE CHILD SITE ELIGIBILITY STANDARDS

The shift from inpatient to outpatient care — accelerated by federal policy favoring lower-cost outpatient settings — has driven sustained growth in hospital child sites, with outpatient volumes projected to increase 20% by 2036.[3] Hospitals have established these outpatient sites to bring oncology, behavioral health, maternal health and other essential services closer to where patients live, and 340B savings generated through these sites help hospitals sustain them and support other services and community programs.

The bill would replace the current framework with a series of new statutory tests that every child site would have to satisfy to purchase 340B drugs. Among other requirements, a child site would need to be wholly owned by and clinically and financially integrated with the parent hospital, meet Medicare provider-based requirements, extend the hospital's financial-assistance policies and be reflected appropriately on the hospital's Medicare cost report. The bill also would generally require a child site to be located in a community that meets specified vulnerability thresholds, with limited alternatives based on the share of patients who are enrolled in Medicaid, uninsured or are otherwise low income. Together, these requirements would make a child site's continued 340B eligibility dependent on multiple ownership, operational, reporting, geographic and patient-mix criteria rather than on whether it is a legitimate hospital outpatient facility providing needed care to the community.

It is unclear what such rigorous and specific standards are intended to achieve when existing HRSA child site registration requirements already ensure eligible child sites

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[3] https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/d68f76ac86a74bc286889f37eba3d3fb

must be recertified annually and meet Medicare provider-based status requirements under 42 C.F.R. 413.65. In addition, imposing these standards could disqualify existing hospital outpatient clinics that serve medically vulnerable patients but do not meet each of the bill's prescribed requirements. For example, a clinic could be deemed ineligible because its location falls just outside a qualifying vulnerability threshold, its payer mix differs slightly from that of the hospital's on-campus clinics, or a newly opened or acquired site has not yet appeared on the hospital's most recently filed Medicare cost report due to the timing of cost report filings. Loss of 340B eligibility at these sites would reduce the resources hospitals need to offset high drug costs and maintain services that often operate with limited or negative margins, potentially forcing hospitals to scale back services, delay expansion into underserved communities, or reconsider whether certain outpatient sites can remain open.

The AHA therefore urges revisions to these provisions so that child-site eligibility is based on clear, durable and administrable standards. A site should qualify when it is part of the 340B hospital, satisfies applicable Medicare provider-based requirements already reviewed by the Centers for Medicare & Medicaid Services, and furnishes meaningful outpatient services to the hospital's patients. While geographic indices and site-level payer-mix measures may provide useful context in evaluating access to care, we do not believe they should be used as the basis for imposing rigid eligibility conditions that override a hospital's assessment of where care is needed.

RECONSIDER PATIENT AFFORDABILITY MANDATES

Hospitals share the goal of helping patients afford the medications and care they need, and we support the bill's focus on financial assistance and patient protections. However, patient affordability requirements should complement the 340B program's broader community-wide mission rather than replace it. Every dollar saved through the 340B program ultimately benefits patients, whether by directly reducing prescription costs or by sustaining services such as oncology care, behavioral health, maternal health, medication management and transportation assistance. A uniform, federally prescribed affordability formula — applied rigidly across hospital locations and contract pharmacies without regard to existing state laws and hospital financial-assistance obligations — ignores the other healthcare needs of the patients and communities each hospital serves and could force hospitals to divert resources from other essential services. We believe that flexibility to use 340B savings according to community need, paired with the bill's existing public reporting requirements, is the most effective way to ensure patient benefit while preserving hospitals' ability to serve their broader communities.

MAKE REPORTING PROPORTIONATE AND TWO-SIDED

340B hospitals have long recognized and supported the importance of transparency in the 340B program, and many voluntarily and publicly report estimated 340B savings and how those savings are used to support patients and communities. However, 340B hospitals believe that transparency measures should be meaningful, non-duplicative of

existing reporting requirements and limit provider burden. We are concerned the bill's transparency requirements would not achieve these goals. The bill would require covered entities to report annually on their estimated 340B savings and uses; patient and prescription counts by payer; charity care, Medicare and Medicaid shortfalls and program operating costs; patient financial demographics and access policies; and information on child sites, contract pharmacies, third-party administrators and governmental contracts. The bill also includes a requirement for the Department of Health and Human Services Secretary to publish both aggregate and hospital-specific data publicly on an annual basis.

Any additional reporting framework should build on — rather than duplicate — information hospitals already provide through Medicare cost reports, IRS Form 990 filings, HRSA's annual recertification process and public registration of child sites and contract pharmacies. Requirements should be standardized, auditable and proportionate to their oversight value, while protecting patient and proprietary information and recognizing the full range of patient and community services supported by 340B savings.

Transparency also must be balanced across the program: Comparable requirements should apply to drug manufacturers, including greater visibility into pricing practices and price increases, as well as to payers and PBMs whose policies can affect whether 340B resources remain available for patient care. A meaningful transparency framework that includes all stakeholders would give policymakers a complete view of the program without diverting hospital resources from the communities 340B is intended to support. Therefore, we urge the sponsors to modify these reporting requirements to ensure they are not duplicative of existing requirements and ensure that transparency measures are placed on drug manufacturers as well.

ENSURE BALANCED PROGRAM INTEGRITY REQUIREMENTS

The bill would expand oversight, auditing, corrective-action and data-exchange requirements across the 340B program. We believe effective federal oversight is essential, but it should apply equally to covered entities, manufacturers, pharmacy benefit managers, payers and other stakeholders. Audit and data-exchange requirements should be uniform, federally supervised, limited to program-integrity purposes, and designed to protect patient and proprietary information. They also should include fair opportunities to correct valid compliance concerns before penalties or program restrictions are imposed.

SUPPORT PAYER AND PBM NONDISCRIMINATION PROTECTIONS

The AHA appreciates the bill's payer and PBM nondiscrimination protections, which are essential to ensuring that 340B savings remain with 340B hospitals to maintain, improve and expand access to patient care. The bill appropriately would prohibit discriminatory reimbursement, fees, clawbacks, audits and network terms; patient steering; coverage

or contracting restrictions based on 340B status; and requirements that hospitals identify 340B claims outside the federal clearinghouse or share 340B savings. We also support meaningful federal enforcement, including civil monetary penalties, to prevent payers and PBMs from undermining covered entities' participation in the program or limiting patients' access to needed medications or their preferred pharmacies.

CONCLUSION

We appreciate your bipartisan leadership and continued recognition of the 340B program as a vital resource for patients and providers. The SECURE 340B Act includes provisions that address important concerns, including manufacturer restrictions on contract pharmacies, payer and PBM discriminatory practices, HRSA oversight capacity and the need for clear federal standards. At the same time, several provisions would benefit from revision to ensure that new requirements are workable, appropriately balanced and do not unintentionally reduce access to medications, outpatient services or other essential care supported by 340B savings.

We respectfully urge you to revise the patient and child-site definitions to preserve flexibility for modern care delivery, replace the affordability mandate with a more flexible approach and ensure reporting requirements are meaningful, proportionate and equally applied to all program stakeholders.

We look forward to working with you to ensure that any final legislation protects patients, strengthens accountability, preserves access to care and maintains the flexibility hospitals need to meet the needs of the communities they serve. Please contact me directly if you have any questions, or have a member of your team contact Aimee Kuhlman, group vice president of advocacy and grassroots, at akuhlman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President