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Advancing Health in America

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Submitted electronically via 340bforpatients@help.senate.gov

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The Honorable Bill Cassidy, M.D.
Chairman
Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

Re: 340B Drug Pricing Integrity and Affordability for Patients Act (340B for Patients Act) Discussion Draft

Dear Chairman Cassidy:

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 340B Drug Pricing Integrity and Affordability for Patients Act (340B for Patients Act) discussion draft. While we share your goals of strengthening program integrity, improving accountability and ensuring that patients have access to medications they need, we are concerned that the discussion draft 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 served as a critical tool to help eligible hospitals expand access to care and reduce overall healthcare costs for underserved patients and communities across the country. The program enables eligible hospitals to stretch limited federal resources by purchasing outpatient drugs at discounted prices, allowing them to reinvest savings directly into patient care and essential services reflecting the unique needs of those they serve.

Importantly, 340B is not a federal spending program. It does not rely on taxpayer appropriations and does not increase federal healthcare expenditures. Instead, it operates by requiring drug companies that choose to participate in Medicaid and Medicare Part B to provide discounts to hospitals that care for a disproportionate share of low-income, uninsured, rural and medically complex patients. Hospitals use 340B savings to increase access to care in ways that directly lower systemwide costs. These investments include providing free or reduced-cost medications for uninsured patients, maintaining outpatient oncology and specialty clinics, expanding mental health and

substance use disorder services, funding medication management programs and offering preventive services. By supporting early intervention, continuity of care and medication adherence, 340B helps prevent avoidable hospitalizations and emergency department visits — actions that drive up costs for patients, payers and communities.[1]

Hospitals support reasonable, workable reforms that protect the 340B program for the patients and communities it was designed to serve. However, the current discussion draft 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 discussion draft provisions follows.

PROTECT THE UPFRONT DISCOUNT MODEL

This discussion draft would allow drug companies the option of making 340B prices available as upfront prices, through retrospective rebates or through a claims data repository. This would create enormous administrative burdens on 340B covered entities as they would be forced to manage multiple, different systems based on the mechanism chosen by each drug company. Moreover, the AHA opposes efforts to move to a rebate model as it would fundamentally change the structure of the 340B program. Requiring hospitals to purchase drugs at full price and wait for manufacturers to approve and issue rebates would create significant cash-flow challenges, particularly for rural hospitals, safety-net hospitals and other financially vulnerable providers. It also would give manufacturers greater control over whether and when a hospital receives a statutorily required discount.

The proposed requirements to submit claims within 30 days, maintain separate physical inventories and provide additional attestations would be unworkable to implement across complex hospital pharmacy operations. These requirements could lead to delayed or denied discounts based on technical errors rather than actual program violations. Any legislation should reaffirm that manufacturers must provide the 340B price at the point of purchase. Hospitals should not be required to provide drug companies interest-free loans while waiting for drug companies to decide whether to honor their statutory obligations.

The AHA is committed to ensuring 340B program integrity and transparency, but the rebate model is a solution in search of a problem that does not exist. If the goal is to create a mechanism that improves transparency and program integrity, we support the creation of a neutral, third-party clearinghouse model that would strengthen the government's oversight of the 340B program, minimize administrative burdens for all stakeholders and ensure continued access to upfront 340B discounted pricing while mitigating any unintended consequences for access to care.

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[1] https://www.sciencedirect.com/science/article/pii/S2667276623000768

PRESERVE THE BROADER PURPOSE OF 340B

The draft would allow hospitals to retain the upfront discount model only if they agree to pass on the full value of every 340B discount directly to individual patients. In addition, the draft would require 340B hospitals to implement a federally prescribed, income-based sliding fee scale for certain patients receiving 340B drugs. These requirements would extend to hospital locations, child sites, entity-owned pharmacies and contract pharmacies, and hospitals would have to publicize and annually submit their policies for federal review.

While the AHA supports efforts to help patients afford their medications, this approach overlooks the purpose and structure of the 340B program. Moreover, we respectfully reject the premise that the current structure of the 340B program does not ensure direct patient benefit. Every dollar saved through the program ultimately creates direct patient benefits whether through directly defraying the high cost of prescriptions or through supporting critical patient care services, such as behavioral health treatment, oncology services, maternal health programs, transportation assistance, mobile clinics and access to specialty services like hepatology and gastroenterology in rural areas. As a result, forcing hospitals to use the entirety of their 340B savings on discounting drug prices ignores the other health care needs of the patients and communities served by the hospital. In addition, patient affordability requirements should complement the program's community-wide mission, not replace it. We believe that flexibility to use 340B savings in a manner that addresses the unique needs of the patients they serve is the most effective mechanism to ensure patient benefit.

AVOID ARBITRARY CONTRACT PHARMACY RESTRICTIONS

340B hospitals' partnerships with local and specialty pharmacies have long been recognized as a key component of the 340B program. These arrangements allow patients access to their prescribed medications at their local community pharmacy or through local and mail-order specialty pharmacies. The accessibility of community pharmacies to many Americans presents a convenient, familiar and dependable source of care. This is especially true for those living in rural communities or who lack easy access to transportation. In addition, rural hospitals often lack the resources to operate their own pharmacies, so they rely on a network of contract pharmacies to ensure access to prescribed medications and 340B savings. Data show that 80% of rural hospitals operate contract pharmacies.[2] In addition, hospitals have contracted with pharmacies in 82% of U.S. counties with food insecurity, 77% of counties with the highest diabetes prevalence and 70% of counties that report poor health.[3] While the

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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*.

AHA appreciates the draft's recognition of contract pharmacies in statute, the draft's proposal to significantly limit the use of contract pharmacies through a five-pharmacy cap and other geographic and mail-order restrictions would harm access to medications for the very patients this draft is intended to protect.

Contract pharmacies are especially important for patients who live far from a hospital, require specialty medications, lack reliable transportation or rely on pharmacies located near their homes or workplaces. The draft's arbitrary numerical cap does not account for differences in geography, hospital size, patient population, pharmacy availability or specialty-drug needs. Further, limiting use of mail-order arrangements for critical access hospitals and sole community hospitals ignores the reality that larger hospitals, such as academic medical centers, are often the sites of care that are most likely to treat medically complex patients from across the country and use specialty medications that may be in limited distribution. In addition, the draft creates a rigid "three strikes and you are out" policy that would terminate a pharmacy relationship for technical or minor violations, even when patients depend on that pharmacy for access to medication. Hospitals and pharmacies also should have an opportunity to correct valid compliance concerns before termination occurs.

Hospitals need maximum flexibility in establishing relationships with community and specialty pharmacies to respond to the varied needs and locations of their patients. They are best equipped to decide which local, specialty, mail-order and other pharmacies they need to establish arrangements with to meet the needs of their patients, ensure medication adherence and the continuum of care. In some cases, hospitals are responsible for patient care across a wide catchment area that can span hundreds of miles and cross state lines. Given the potential for expansive geographic reach, hospitals may need to establish contract pharmacy relationships that appear far away from the main hospital but are in fact in areas where their patients live and need access to their prescribed medications. Moreover, certain specialty pharmacies are only located in certain areas and warehouse certain medications that are in limited distribution and unavailable through other pharmacies. For example, many hospitals across the country contract with a Walmart specialty pharmacy located in Orlando, Fla., because it serves as a central distribution hub for certain medications their patients require and that are only available through that pharmacy. Therefore, these arbitrary limits and restrictions on the use of contract pharmacies will diminish the ability of 340B hospitals to ensure access to medications for their patients.

REVISE THE CHILD SITE PROVISIONS

One of the most significant outgrowths of the increased use of technology and advances in clinical medicine is the shift from inpatient hospital care to outpatient hospital care. This shift has been accelerated by government regulations promoting the move of certain services (especially low-cost and less complex services) that had been traditionally performed in the inpatient setting to the outpatient setting.

These broader systemwide trends have created an environment for increased demand for outpatient care and the critical need for outpatient clinics or child sites and these trends are projected to continue. Recent research has shown that outpatient volumes are projected to increase by 20% by 2036.[4] Consistent with the goals of the 340B program, these outpatient facilities allow 340B hospitals to expand access to their services. The scope of services offered at child sites varies based on the needs of the community. In some cases, child sites offer a broad range of care; in other cases, they offer a single service like an infusion clinic where patients can access chemotherapy necessary for cancer treatment.

The proposed child site standards included in the draft could disqualify hospital outpatient clinics that provide essential services to underserved communities. Under the draft, child sites would have to satisfy numerous requirements related to Medicare cost reports, provider-based status, ownership, geographic shortage area designation, charity care and Medicare and Medicaid underpayments. These tests may not accurately reflect the needs of the patients served by a particular clinic.
For example, a clinic could serve a medically vulnerable population but fail an eligibility test because it is not located in a formally designated shortage area or because its payer mix differs from the hospital's on-campus clinics. New clinics also may not immediately appear on a filed Medicare cost report for several months due to the idiosyncrasies of the cost reporting and hospital fiscal year timelines. Eligibility should be based on whether the site is part of the 340B hospital, meets applicable provider-based standards that are already established and vetted by the Centers for Medicare & Medicaid Services and furnishes meaningful outpatient services to the hospital's patients. Establishing a set of arbitrary standards that limit use of child sites under the 340B program will diminish the ability of hospitals to meet the demand for care that patients require.

REVISE THE PATIENT DEFINITION

The AHA supports establishing a clear and consistent patient definition. However, the definition must be durable enough to account for modern care delivery mechanisms through virtual care and remote monitoring, including referrals, integrated care teams, specialty pharmacy services and ongoing treatment of chronic conditions. We believe the current standard established by the Health Resources and Services Administration (HRSA) through its 1996 guidance continues to provide the flexibility needed to respond to a dynamic healthcare delivery environment, while also giving HRSA a clear and enforceable standard to ensure program integrity. On the contrary, the draft's proposed rigid requirement tying every prescription to a particular outpatient encounter or referral could exclude legitimate hospital patients whose treatment continues over time or involves multiple practitioners. Moreover, codifying such stringent requirements could

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

force this issue to become legislated repeatedly as care delivery changes, particularly with the advent of artificial intelligence and other emerging technologies.

For example, when HRSA implemented its 1996 patient definition guidance, telehealth did not exist. Now, it is an important and ubiquitous method of care delivery. The flexible and broad definition currently permitted by HRSA has allowed the 340B program to continue to benefit hospitals and their patients in the face of these changes. On the other hand, a restrictive patient definition that would limit the types of services eligible for 340B pricing and establish an ambiguous "meaningful relationship" standard would create additional uncertainties and jeopardize the use of telehealth (or future service methods) for 340B eligible patients. Therefore, the restrictive patient definition standard proposed under this bill would not be workable.

MAKE REPORTING MEANINGFUL, PROPORTIONATE AND EQUAL ACROSS ALL STAKEHOLDERS

Hospitals have long supported and recognized the importance of transparency in the 340B program to ensure it continues to meet the purpose established by Congress. For example, over 1,400 340B hospitals have voluntarily committed to the AHA's Good Stewardship Principles sharing publicly their estimated 340B savings and how those savings are used to address the healthcare needs of their community. However, the proposed reporting framework in the draft would establish overly burdensome, duplicative and meaningless data reporting that risks producing misleading information that could be used to undermine or misrepresent the value of the 340B program.

As Congress considers what, if any, additional transparency measures are needed, we should first consider the measures that already exist. Under the current requirements that exist across state and federal regulations, 340B hospitals already report a variety of information to demonstrate their commitment to providing care to underserved populations. Under both federal tax requirements and Medicare rules, 340B hospitals report uncompensated care costs, charity care costs, under-reimbursed care costs and other benefits provided to the communities they serve through both their annual Medicare cost reports and the IRS 990 form required for tax-exempt organizations.

Of note, the most recently available IRS 990 data show that 340B hospitals provided nearly $100 billion in community benefits in 2022, a nearly $32 billion (47%) increase from 2019. Further, the increase in community benefits has outpaced the increase in 340B discounts that hospitals have received, illustrating the outsized nature of 340B hospitals' commitment to expanding access to care for the patients they serve. In addition to these data that are publicly available, HRSA requires separate reporting during its annual 340B hospital certification process, including registration and public reporting of each hospital child site and contract pharmacy arrangement. Drug sales purchased under the 340B program also are tracked by HRSA's 340B prime vendor, Apexus, and reported publicly on an annual basis. Together, these data already provide

the federal government and the public ample evidence to assess the value of the 340B program and whether 340B hospitals are meeting Congress' goals.

Instead of relying on these existing data, the draft seeks to impose additional reporting requirements. For example, the draft would require reporting on volume of prescriptions and charity care costs at both the parent-hospital and individual child site levels, with the scope of additional requirements increasing with the hospital's revenue. It also would require public reporting of a hospital's "340B margin," calculated as the difference between aggregate payments received for 340B drugs from public and private payers and the costs incurred for acquiring those drugs, less the costs incurred by the hospital to operate their 340B program. Such a calculation would not only overstate the 340B benefit achieved by the hospital but would fail to meaningfully capture the range of programs and services supported by those savings. Therefore, presenting the resulting number as the hospital "margin" could create an incomplete and distorted picture of the program.

We believe that any reporting requirements should be standardized, auditable and focused on information that demonstrates the program's value. They should avoid duplicating existing federal reporting, protect proprietary information and recognize the full range of patient and community services supported by 340B.

CREATE BALANCED OVERSIGHT

Hospitals support strong federal oversight and meaningful enforcement against program violations for all stakeholders. Oversight, however, must apply equally to 340B covered entities and drug companies. In addition, any legislation should ensure that oversight rests solely with the federal government and is not delegated to drug companies or 340B covered entities that have self-interested goals. This draft falls short of this standard.

The draft substantially expands manufacturer and federal audit authority and gives manufacturers greater control over the discount-delivery process. The draft gives little to any relief or ability to seek redress for 340B covered entities. Any legislation also should establish clear manufacturer obligations, prohibit the ability of unilateral restrictions on accessing 340B pricing or imposing data requirements, and impose meaningful consequences when manufacturers overcharge covered entities or fail to provide statutorily required discounts.

Further, manufacturer audits should be conducted under uniform federal standards, protect patient and proprietary information, be limited in scope to the alleged violations, prevent duplicative requests and include a fair appeal process with federal oversight.

CONCLUSION

We appreciate your interest and commitment to improving the 340B program and welcome continued dialogue on policies that strengthen accountability, protect patients and preserve access to care. However, the discussion draft in its current form would undermine access to care for the very patients it is purportedly designed to protect. We believe this draft requires substantial revision to avoid shifting control of the program to drug manufacturers, reducing patients' access to pharmacies and outpatient clinics, and diverting hospital resources away from care.

We respectfully urge you to preserve the upfront discount model, replace arbitrary access restrictions with patient-centered standards, revise the child site and patient definitions, develop proportionate reporting requirements, and establish balanced accountability for both covered entities and manufacturers.

We appreciate your consideration of our comments, and we look forward to working with you to ensure that any final legislation strengthens — not diminishes — the ability of 340B hospitals to serve patients and communities. Please contact me directly if you have any 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