NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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August 26, 2026

The Honorable Bill Cassidy, MD
U.S. Senate Health, Education, Labor, and Pensions Committee
428 Senate Dirksen Office Building
Washington, DC 20510

RE: Discussion Draft - 340B Drug Pricing Integrity and Affordability for Patients Act

Dear Senator Cassidy and members of the Senate HELP Committee:

The National Infusion Center Association (NICA) is a nonprofit organization formed to support community-based infusion centers caring for patients in need of provider-administered medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in safe, efficient, and cost-effective alternatives to hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in safety across care settings, and foster patient access to the highest-quality, lowest-cost setting.

NICA's members administer medications to patients – including Medicare beneficiaries – with serious conditions such as autoimmune disease, which is lifelong and can result in permanent disability if not managed appropriately upon diagnosis. Fortunately, the treatment of autoimmune disease, including such conditions as rheumatoid arthritis, psoriasis, and lupus, has come a long way in that there are now specialty biologics that enable patients to manage their condition, in many cases with such success that these patients are able to fully engage in activities of daily living and/or remain employed in the same way they were prior to diagnosis.

We appreciate the opportunity to provide comments on the discussion draft for the *340B Drug Pricing Integrity and Affordability for Patients Act* and how these reforms will impact infusion providers nationwide as well as the patients they serve.

340B Drug Pricing Program: Overview

The 340B Drug Pricing Program was originally created to improve medication affordability for underserved patients by allowing eligible healthcare entities to purchase drugs at a discount. Established under the Veterans Health Care Act of 1992, the 340B Drug Pricing Program under section 340B of the Public Health Service (PHS) Act aims to address an unintended consequence created by the Medicaid Drug Rebate Program under the Omnibus Budget Reconciliation Act of 1990. The program was designed to improve access to medications for vulnerable patients by re-establishing a discount program for our nation's safety-net providers. The program required manufacturers to sell covered outpatient drugs at or below

statutorily defined discount prices (called "340B ceiling prices") to covered entities in order to have drugs covered by Medicaid.

However, the program has deviated significantly from its intended purpose. Current law nor guidance specify exactly how these savings should be allocated by covered entities, nor does it address what eligible providers may charge. Many payers—including Medicare and, in some cases, Medicaid—reimburse at amounts that are much higher than the acquisition cost of the 340B drugs, and covered entities may generate revenue from the "spread" between the cost at which the drug was acquired and the price at which the drug is reimbursed above acquisition cost.

As a result, covered entities can purchase outpatient drugs at steep discounts, typically between 25-50% off the drug's average price.[1] At times, the calculated ceiling price can actually be less than $0.01, setting the cost of the drug through 340B at a penny. This creates extreme discounts that cannot be found elsewhere in the market, which create significant savings for covered entities. These steep discounts occur because the 340B covered entity charges the patient's payer for reimbursement well above the acquisition cost and keeps the difference. In some instances, disproportionate share hospitals target commercially insured patients to sell their 340B discounted drugs to, bill the insurer for an enormous markup on the drug, and pocket the entire difference without sharing any of the savings with the patient, their insurer, or vulnerable (i.e., uninsured) patients being treated by the covered entity.

Instead of ensuring that savings benefit patients, large tax-exempt hospitals, private equity-backed organizations, and contract pharmacies have exploited these regulatory loopholes to generate substantial profits, often at the expense of the very patients the program was designed to help.

Establishing a Patient Definition (Section 4)

The 340B statute vaguely defines the eligibility criteria for what constitutes a "patient," providing ample room for interpretation. Currently, the only limitation within the 340B statutory language is that a covered entity cannot "resell or otherwise transfer" a 340B drug to "a person who is not a patient of the entity." The Health Resources and Services Administration (HRSA) requires that the "patient" have an ongoing relationship with the entity, but has failed to establish any further eligibility requirements. Thus, in its current form, the 340B program could serve a billionaire whose favorite doctor happens to work in a DSH outpatient department.

Furthermore, 340B covered entities are not required to pass along their discounts *directly* to patients or, nor are they required to demonstrate their investments in outpatient support programs for vulnerable patients. Consequently, there is no oversight to ensure that covered entities use program savings to improve access to outpatient drugs for the vulnerable patient populations the program was intended to serve. This vagueness has resulted in an increased risk of program abuse and significant variation across entities in whether patients are benefiting from the 340B program.

NICA strongly supports the creation of a patient definition within the *340B for Patients Act,* which requires that the patient:

- has received an outpatient health care service at the covered entity within the preceding two years; and

[1] Qualify Health. "How does 340B Pricing Work? Answers Healthcare Leaders Need." May 2025.

- has a relationship with the covered entity, including auditable medical records, that demonstrates the existence of a patient relationship, and maintains records for a period of at least three years; and
- received the prescription for the covered outpatient drug from a practitioner as a result of outpatient services or as a referral.

These parameters will provide greater clarity and accountability within the program, ensuring the program serves only patients intended under the original law.

Reigning in Contract Pharmacy Growth (Section 5)

Originally, HRSA limited the use of contract pharmacies to entities that did not have in-house pharmacies. In 2001, HRSA allowed a select number of 340B-covered entities to contract with multiple pharmacies, making way for national pharmacy chains – such as Walmart and CVS Health – to participate in the program. By 2010, HRSA guidance established that eligible entities, even those with in-house pharmacies, could utilize an *unlimited* number of contract pharmacies.[2] Due to the program expansion permitted under this guidance, the number of participating 340B contract pharmacies from 1.3% of all retail pharmacies in 2009 to 40.9% of all retail pharmacies by 2022.[3] By 2025, the five biggest pharmacy chains[4] accounted for 77% of all 340B contract pharmacy relationships with covered entities.[5] Profit margins for these covered entities average around 72% on 340B medicines, allowing covered entities and contract pharmacies to obtain $13 billion in gross profits in 2018.[6] Over 50% of the profits from 340B program participation is retained by three national pharmacies: Walgreens, Walmart and CVS Health, as well as Cigna's Accredo specialty pharmacy.[7]

The mass growth of this program is highly concerning. However, more alarmingly, this growth is not happening in neighborhoods where our most vulnerable patients live. Studies show that the percentage of 340B contract pharmacies in the highest-income neighborhoods increased by 5.0 percentage points, while the percentage of 340B pharmacies in the lowest-income neighborhoods *declined* by 5.6 percentage points.[8] Meanwhile, profit margins for 340B contract pharmacies are 3.3 times higher than independent pharmacies, and drug price markups at 340B hospitals are 6.6 times higher than at independent clinics.[9] These discrepancies indicate a concerted focus on profits instead of developing the program in neighborhoods in most need of healthcare services.

NICA strongly supports the inclusion of contract pharmacy parameters within the *340B for Patients Act,* which limits contract pharmacy agreements with disproportionate share hospitals by:

- restricting the number of contract pharmacy agreements to five per covered entity; and
- requiring the contract pharmacy to be located within the service area of the covered entity.

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[2] Federal Register. "Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services." March 2010.
[3] JAMA Health Forum. "Trends in 340B Drug Pricing Program Contract Growth Among Retail Pharmacies From 2009 to 2022." August 2023.
[4] Cigna, CVS Health, UnitedHealth Group, Walgreens, and Walmart
[5] Drug Channels. "The 340B Contract Pharmacy Market in 2026: A Maturing Industry Dominated by Big Chains and PBMs." June 2026.
[6] Berkeley Research Group. "For-Profit Pharmacy Participation in the 340B Program." October 2020.
[7] Ibid.
[8] JAMA Health Forum. "Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics." June 2022.
[9] Alliance for Integrity and Reform of 340B. "Overview." 2025.

The legislative draft also restricts dispensing for federal grantees only by mail order pharmacies within the service area. Distinguishing different parameters for federal grantees versus hospitals will help ensure that the most flagrant abusers of the program are reigned in.

Establishing Baseline Transparency Requirements for Disproportionate Share Hospitals (Section 6)
There are many covered entities that use their 340B revenue as the program intended to subsidize charity care, uncompensated care, and programs to improve access to health care for vulnerable patients. However, the most problematic behavior we have observed in the 340B market stems from disproportionate share hospitals. These covered entities are supposed to serve a disproportionately high number of low-income individuals, for which they receive additional Medicare payments. Unlike the other entities specified in the statute, disproportionate share hospitals do not exclusively serve a narrowly defined patient population or rural locations, and the statute does not provide any further definition for patient eligibility.

While there are some 340B disproportionate share hospitals that offer significant charity care, at least 36% of disproportionate share hospitals offered less than 1% of their total operating costs,[10] falling bar below the national average on charity care for 69% of 340B hospitals.[11,] While the overall mission of 340B aligns with charity care, the statute neither defines "charity care" nor does it require covered entities to report the level of charity care they provide. Greater transparency is clearly needed in this space.

Yet, there are virtually no transparency or reporting requirements for 340B entities or contract pharmacies. Congress also failed to establish any mechanisms to monitor or calculate program savings or specify how program savings are to be used. Consequently, there is great variation in how program savings are utilized across covered entities—although federal grantees are restricted in how they use program funds due to other federal grant requirements. Without comprehensive information, it will remain difficult to provide adequate oversight of the program.

NICA strongly supports the inclusion of transparency requirements for disproportionate share hospitals on each covered entity and child site within the *340B for Patients Act*. Requirements in the draft to report on the following provisions will provide much needed insights into program operations and how the program directly supports vulnerable patients, including:

- the margin generated on covered out-patient drugs; and
- statistical information about patients served; and
- the total costs incurred for charity care; and
- use of margin generated on covered outpatient drugs.

The Committee may also want to consider additional data points such as: the volume of 340B drugs administered to commercially insured patients; what price commercially insured patients' coinsurances are based on; and disclosure of ownership of pharmacies used.

Finally, NICA supports granting HRSA with greater authority and enforcement of the law through audits. HRSA conducts less than 200 reviews[12] annually out of 42,000 covered entities nationwide.[13] Even for

[10] Alliance for Integrity and Reform of 340B. "Charity Care at 340B Hospitals is on a Downward Trend." October 2023.
[11] Ibid.
[12] ADVI. "ADVI Analysis: HRSA 340B Covered Entity Audits." March 2025.
[13] Commonwealth Fund. "340B Drug Pricing Program: How It Works, Why It's Controversial." August 2025.

these extremely limited audits, HRSA lacks sufficient authority to clarify program requirements, adequately oversee the program and penalize violations. Instead, program participants are largely left to self-audit, which is alarming since 2025 340B purchases totaled over $100,000,000,000.[14] This is completely inadequate and requires little accountability by 340B covered entities.

Ensuring Affordability is an Essential Patient Protection (Section 7)

As providers who administer complex specialty medications daily, NICA members are acutely aware that the price of a drug and what a patient actually pays out of pocket are two entirely different problems. Unfortunately, patients never benefit from savings that occur upstream in the supply chain. Instead, their copay, coinsurance, or deductible at the pharmacy counter or infusion chair far too often remain the same. When policies focus on discounts, rebates, or reimbursement mechanisms that never touch what the patient is billed, those savings can be absorbed anywhere along the supply chain—by manufacturers, health plans, or the entities purchasing the drugs—without ever reaching the person actually taking the medication. When patients are unable to afford their medications, they may choose to delay or abandon critical therapies.

Therefore, it's critical that policies are designed to directly reduce patient cost-sharing at the point of care, not simply assumed to trickle down from savings captured elsewhere in the system. For these reasons, NICA greatly appreciates the inclusion of patient affordability protections within the bill, including:

- a maximum out-of-pocket obligation based on family income; and
- mandatory discounts offered by disproportionate care hospitals that limit patient out-of-pocket costs; and
- mandatory affordability assistance to eligible patients through the covered entity or contract pharmacy.

Reigning in Child Site Expansion and Hospital Consolidation

Standalone hospitals are increasingly pursuing mergers/affiliations with other hospitals, hospital systems, outpatient provider groups, and physician-owned practices. In fact, as of 2024, nearly half (47%) of all U.S. metropolitan areas had inpatient hospital markets fully controlled by just one or two health systems.[15] NICA is deeply concerned by a trend among nonprofit, tax-exempt disproportionate share hospitals that are using accumulated revenue from 340B-discounted drugs and tax savings to acquire community-based, physician-owned practices in specialties that administer a high volume of expensive, provider-administered drugs such as oncology, rheumatology, gastroenterology, and neurology.

Acquisition trends show that hospitals seek out affluent communities to maximize this arbitrage opportunity, expanding their 340B market share by gaining access to a higher number of commercially insured patients.[16] Once acquired, the practices are turned into "child sites," or off-site outpatient facilities,[17] even though the patient population does not reflect the disproportionate share percentage of the parent entity. As of 2023, approximately 75% of all registered covered entities were child sites.[18]

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[14] Health Resources & Services Administration. "2025 340B Covered Entity Purchases." July 2026.

[15] Fierce Healthcare. "Nearly half of US hospital markets entirely controlled by 1 or 2 health systems: KFF." March 2026.

[16] Health Serv Res. "Expansion of 340B Disproportionate Share Hospitals in the United States From 2010 to 2022." March 2025.

[17] Health Resources and Services Administration. "How Hospitals Register for the 340B Program." September 2022.

[18] U.S. Government Accountability Office. "340B Drug Discount Program: Agency Oversight Has Improved, but Actions Needed to Address Weaknesses." October 2025.

This ubiquitous acquisition and consolidation within the healthcare marketplace threatens the viability of local office-based infusion providers. These independent practices and infusion centers are already forced to navigate a volatile reimbursement landscape, in which competition is significantly distorted in favor of hospitals. Since most practices are not eligible for 340B discounts and are not exempt from taxation like many hospitals, they have an increasingly difficult time competing with these largest disproportionate share hospitals. This price differential has created a widening profit disparity between hospitals and independent physician practices that is distorting competition.

NICA believes actions must be taken to limit the deluge of hospital consolidation by disproportionate share hospitals in the 340B program. NICA thanks you for recognizing the need to address this and strongly supports provisions within *340B for Patients Act* that restricts purchases of 340B drugs to only registered child sites and prohibits the transfer of drugs to other locations. Furthermore, we appreciate new registration requirements for off-campus outpatient facilities that require the facility to:

- be wholly owned by the covered entity;
- provide out-patient health services that are not limited to only dispensing, administering and furnishing 340B drugs;
- adhere to all charity care and sliding fee scale policies;
- be located in an area with a shortage of personal health services; and
- meet charity care metrics.

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The market distortions created by the opacity of the program and rapid expansion of the 340B Drug Pricing Program have led to unintended consequences for our nation's sickest and most vulnerable patients. We are encouraged to see that the Senate HELP Committee under Sen. Cassidy's leadership is working to refocus the program, eliminate potential abuse, and ensure that vulnerable patient populations actually benefit from the program.

Thank you for the opportunity to comment on this important issue. We would welcome the opportunity to connect with you if we can provide any other information about this important policy area. Please do not hesitate to contact me, should you have any questions or wish to further discuss this issue: Brian.nyquist@infusioncenter.org

Sincerely,

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Chief Executive Officer
National Infusion Center Association