The Center for Healthcare Affordability

A Project of the Institute for Legislative Analysis

August 28, 2026

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

Re: Comments of the Center for Healthcare Affordability in Support of the 340B Drug Pricing Integrity and Affordability for Patients Act Discussion Draft

Dear Chairman Cassidy,

On behalf of the Center for Healthcare Affordability (CHA), I appreciate the opportunity to comment on the 340B Drug Pricing Integrity and Affordability for Patients Act, commonly referred to as the 340B for Patients Act.

CHA is a project of the Institute for Legislative Analysis, and serves as a national healthcare policy research initiative focused on developing market-oriented solutions that improve affordability, competition, innovation, and patient access. CHA maintains an extensive healthcare policy database and has developed a comprehensive Healthcare Reform Prescriptions framework examining five of the most significant challenges affecting healthcare affordability in the United States.[1] The 340B Program is an area CHA has extensively examined and developed proposals under *CHA's Rising Medical Treatment Costs reform framework*.

CHA supports the discussion draft as a substantial and constructive step toward restoring patient focus, accountability, and basic program integrity to 340B. We particularly commend your years-long examination of how 340B revenue is generated, distributed, and used, as well as your willingness to address a program that has expanded far beyond its original scope.[2]

Center for Healthcare Affordability
300 Independence Ave, S.E.
Washington, D.C. 20003

The Need for Reform

The 340B Program was structurally flawed from its inception. Rather than transparently appropriating funds to support care for vulnerable patients, Congress created an indirect, institution-based subsidy by requiring pharmaceutical manufacturers to provide deeply discounted outpatient drugs to qualifying entities as a condition of participation in Medicaid and Medicare Part B.

This design obscures the program's true cost and disconnects eligibility from the financial circumstances of individual patients. A covered entity may purchase a drug at the statutorily discounted price, receive substantially higher reimbursement from a public or private insurer, and retain the resulting margin. Federal law generally does not require that this margin be passed directly to the patient or restrict its use to services for low-income individuals.[3]

The Affordable Care Act subsequently expanded the categories of participating hospitals. At approximately the same time, 2010 guidance from the Health Resources and Services Administration permitted covered entities to establish relationships with multiple contract pharmacies. These changes contributed to extraordinary growth. The number of contract pharmacies increased from approximately 1,300 in 2010 to nearly 20,000 in 2017, according to the Government Accountability Office, and exceeded 32,000 by 2024, according to analysis by the Paragon Health Institute.[4]

Program spending has grown just as dramatically. HRSA reports that covered entities purchased $100 billion in outpatient drugs at discounted 340B prices during 2025, up from $81.4 billion in 2024.[5] CBO found that nearly half of all community hospitals participated in 340B in 2021 and that hospitals and their affiliated facilities accounted for 87 percent of purchases through the 340B Prime Vendor Program.[6]

Growth by itself does not prove abuse. It does, however, heighten the need for clear eligibility standards, reliable claims information, meaningful audits, and public accounting of who benefits. GAO has repeatedly identified deficiencies in federal oversight, including incomplete safeguards against duplicate discounts, inadequate verification that noncompliance has been corrected, and limited assurance that only eligible hospitals participate.[7]

Effects on Affordability and Consolidation

CHA believes the incentives embedded in 340B contribute to both healthcare consolidation and rising costs.

The larger the difference between a drug's discounted acquisition price and its reimbursement, the greater the financial incentive to increase the volume of 340B prescriptions, favor more expensive therapies, acquire physician practices, and move treatment into hospital-owned outpatient settings. CBO has concluded that the

program encourages behaviors that tend to increase federal spending, including the use of more and higher-priced drugs, expansion of services, and greater integration between hospitals and off-site clinics. CBO identified hospital-clinic integration as the largest of three program-specific factors contributing to 340B growth that it examined. [8]

These incentives matter because consolidation is not economically neutral. CBO has separately found that provider consolidation gives hospitals greater bargaining power, resulting in higher prices for commercial insurers and higher premiums. Hospital acquisition of physician practices can also shift services into more expensive outpatient settings where facility fees and higher reimbursement rates apply.[9]

CHA recognizes that many hospitals face genuine financial pressures resulting from inadequate government reimbursement, regulatory mandates, workforce shortages, and other public-policy distortions. Some institutions have consequently become dependent upon 340B revenue. Nevertheless, one flawed policy should not be used to compensate for the effects of other flawed policies. An opaque transfer financed through mandatory manufacturer discounts is not a sound substitute for transparent safety-net funding or reforms that reduce unnecessary burdens on hospitals.

Moreover, the program should not treat pharmaceutical manufacturers as an unlimited financing source. Compelled discounts are not costless, particularly when program growth is increasingly disconnected from individual patient need. Policymakers should account for the effects of these expanding obligations on competition, investment, and the development of future treatments.

Provisions CHA Supports

CHA strongly supports several components of the discussion draft.

First, the statutory definition of a 340B patient is essential. The current reliance on administrative guidance has produced uncertainty and opportunities for inconsistent interpretation. Requiring an actual outpatient-care relationship with the covered entity and a prescription written by an appropriate practitioner would better connect the discount to legitimate patient care and reduce diversion. Equally important, the legislation should establish a sensible and appropriately narrow standard for referrals.

A referral should not allow an individual who receives care principally from unaffiliated providers to be converted into a 340B patient based on a nominal or attenuated connection to a covered entity. Qualifying referrals should reflect a genuine clinical relationship in which the covered entity remains meaningfully involved in and accountable for the patient's care. Without clear limits on what constitutes a qualifying referral, even a strong statutory patient definition could be undermined in practice.[10]

Second, the transparency provisions represent a major improvement. Requiring

covered entities to report information concerning 340B margins, patient populations, insurance categories, charity-care expenditures, and the use of program-generated revenue would allow policymakers and the public to evaluate whether benefits are reaching vulnerable patients. CHA especially supports publication of this information in an electronic, searchable format and by specific covered entity.[11]

Third, the contract-pharmacy guardrails are warranted. CHA's preferred policy would generally limit contract-pharmacy participation to situations in which it is demonstrably necessary to maintain patient access. Nevertheless, the draft's service-area requirements, caps on certain contract-pharmacy relationships, annual recertification, written-contract requirements, and safeguards against diversion and duplicate discounts are meaningful improvements.[12]

Fourth, the eligibility standards for off-campus hospital child sites would help counter incentives for opportunistic expansion. Requiring qualifying facilities to be wholly owned, to provide outpatient healthcare services beyond the administration of medicine, to operate in shortage areas, and to meet charity-care and other patient-service standards would better align eligibility with community need.[13]

CHA also supports the draft's patient-affordability provisions, including sliding-fee protections for qualifying low-income and uninsured patients.

Recommended Revision to Section 2

While CHA supports the overall framework, Section 2 should be strengthened to prevent an exception from undermining the claims-verification reforms that the section is intended to establish.

As drafted, manufacturers would generally be permitted to select among an upfront discount, a retrospective rebate following submission of standardized claims information, or a claims-repository mechanism. The draft would also permit a covered entity that agrees to make outpatient drugs available to its 340B patients at no more than the ceiling price, plus a nominal dispensing fee, to select its preferred payment mechanism instead of using the manufacturer's selection.[14]

CHA supports the objective of ensuring that patients receive the benefit of the discount. However, patient pass-through should not become a means of bypassing prospective claim-level validation. Without additional safeguards, a covered entity could potentially require an upfront-discount model even when the manufacturer has selected a rebate designed to verify patient eligibility, prevent diversion, and detect duplicate Medicaid discounts before funds are transferred.

We therefore recommend that a covered entity be permitted to displace the manufacturer-selected mechanism only when:

- The individual satisfies the statutory definition of a 340B patient;

- Complete standardized claims data are submitted before or contemporaneously with the discount;
- The claim has been screened for Medicaid rebates, other statutory discounts, and potential duplicate-discount liability;
- The full value of the discount or rebate is documented as having been passed to the patient, apart from a permitted nominal dispensing fee; and
- The transaction remains subject to manufacturer and HHS audit, recoupment, and civil-enforcement authority.

At a minimum, Congress should clarify that electing an upfront-discount method does not excuse the covered entity from submitting the same claim-level information that would be necessary under a rebate or claims-repository model. The form and timing of payment should not determine whether eligibility and duplicate-discount protections apply.

This revision would preserve the draft's patient-affordability objective while preventing the exception from swallowing the broader program-integrity rule.

Conclusion

CHA's preferred long-term policy would replace 340B's opaque, institution-based subsidy with transparent assistance directed toward patients and legitimate safety-net needs. Such reform should be paired with the repeal or modification of federal policies that unnecessarily increase hospitals' operating costs, inhibit competition, and encourage consolidation.

Until Congress undertakes that broader restructuring, the 340B for Patients Act offers a necessary improvement over the status quo. Its patient definition, transparency requirements, contract-pharmacy limitations, child-site standards, and patient-affordability protections would bring accountability to a program that has operated for too long without adequate statutory guardrails.

CHA respectfully urges the Committee to advance these reforms while strengthening Section 2 to ensure that patient pass-through provisions cannot be used to circumvent claims verification, duplicate-discount prevention, or manufacturer-selected integrity mechanisms.

Thank you for your leadership on this important issue and for considering our comments.

Sincerely,

Fred McGrath
Executive Director, Center for Healthcare Affordability
A Project of the Institute for Legislative Analysis

Endnotes:

[1] Center for Healthcare Affordability, Healthcare Reform Prescriptions.
[2] U.S. Senate Committee on Health, Education, Labor, and Pensions, “Chairman Cassidy Unveils Landmark Discussion Draft to Fix 340B, Lower Health Costs for American Patients and Families”; official discussion draft.
[3] Congressional Budget Office, Growth in the 340B Drug Pricing Program, September 2025.
[4] U.S. Government Accountability Office, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, June 2018; Paragon Health Institute, “340B: End the Spread”, June 2026.
[5] Health Resources and Services Administration, “2025 340B Covered Entity Purchases”.
[6] Congressional Budget Office, Growth in the 340B Drug Pricing Program, September 2025.
[7] U.S. Government Accountability Office, 340B Drug Discount Program: Agency Oversight Has Improved, but Actions Needed to Address Weaknesses, October 2025.
[8] Congressional Budget Office, Testimony on Growth in the 340B Drug Pricing Program and Its Implications for the Federal Budget, October 23, 2025.
[9] Congressional Budget Office, Hospital and Physician Consolidation and Its Impact on the Federal Budget, May 23, 2024.
[10] U.S. Senate HELP Committee, section-by-section summary of the 340B for Patients Act, Section 4.
[11] 340B for Patients Act discussion draft, Section 6; Heritage Foundation, Bringing Much-Needed Transparency and Accountability to Indigent Care Programs, March 2024.
[12] U.S. Senate HELP Committee, section-by-section summary, Section 5.
[13] Id., Section 8.
[14] 340B for Patients Act discussion draft, Section 2, pp. 10–11; HELP Committee section-by-section summary, Section 2.

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