COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

August 28, 2026

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

Submitted electronically to 340bforpatients@help.senate.gov

Dear Chairman Cassidy,

Thank you for the opportunity to provide comments on the *340B Drug Pricing Integrity and Affordability for Patients Act* discussion draft. The Council for Affordable Health Coverage (CAHC, www.cahc.net) is a broad-based alliance with a singular focus: ensuring all Americans have access to affordable coverage. CAHC advocates for policies that promote competition, choice, and innovation so that premiums and consumer out of pocket costs decrease.

CAHC has long supported reduced drug costs, greater access to drug therapies, and fostering innovation to help treat and cure disease. We appreciate your work that informed this draft, and we support its core goals: refocusing 340B on the low-income and uninsured patients it was intended to serve, adding meaningful transparency, and preventing the waste, diversion, and discount duplication that raises costs for patients, employers, working families, and taxpayers. We support:

- Limiting incentives for consolidation that drives up costs
- Ensuring covered entities pass through drug price discounts to patients
- Ending duplicate discounts and duplicate reimbursement for the same drug
- Rebuilding trust through accountability and transparency in the program

The 340B program has outgrown its original purpose of helping entities better serve low income patients. Many covered entities access discounted prices and never pass those discounts on to consumers. Nothing in current law requires them to. They engage in arbitrage and markup drugs that patients pay inflated cost sharing on. Worse, covered entities are consolidating market power to earn more revenue and profit from 340B spreads. These practices drive up costs for patients, employers and taxpayers with no evidence of benefit to patient care outcomes. We encourage you to go further than the draft in reforming the 340B program and ensure 340B resources are better directed to true safety net providers and low income patients.

Background

When Congress created the 340B program in 1992, it was meant to help safety-net providers stretch scarce resources to care for vulnerable patients. In the decades since, the program has grown far faster than the population it was intended to serve, and too little of the benefit reaches patients directly. HRSA reports that covered entities purchased $100.0 billion in drugs at discounted 340B prices in 2025, up from $81.4 billion in 2024 and $43.9 billion in 2021. The program has more than doubled in four years. The Congressional Budget Office found that 340B grew at an average of 19 percent annually between 2010 and 2021, against roughly 4 percent average annual growth in spending on brand-name drugs and attributed about two-thirds of that increase to factors specific to the program rather than to market wide trends. Federal law, meanwhile, does not require a covered entity to pass any portion of the 340B discount to the patient. When GAO examined this question, 25 of the 55 covered entities it surveyed, including 16 of the 28 hospitals, reported that they did not offer discounts on 340B drugs to low-income, uninsured patients at their contract pharmacies.

The economics of 340B also reward scale. A covered entity purchases a covered outpatient drug at the 340B price and is reimbursed by commercial insurers and Medicare at rates set without reference to that price. The entity retains the difference. Because that margin grows with the number of patients and prescriptions an entity can attach to itself, the program creates a standing financial incentive for hospitals to acquire physician practices, infusion centers, and community oncology clinics and to register them as off-campus outpatient facilities. The acquired site brings its patients, its prescriptions, and its billing into the hospital's 340B footprint, and the same care is thereafter furnished in a higher-cost setting.

- The Congressional Budget Office identifies vertical integration of hospitals with off-site clinics as a principal driver of 340B growth, and testified to the HELP Committee in October 2025 that the program "incentivizes vertical integration of hospitals with outpatient clinics, driving up commercial and Medicare payment rates." CBO reports that hospital off-site clinics registered in 340B grew from 6,100 in 2013 to 27,700 in 2021.
- The Government Accountability Office found in October 2025 that covered entity sites more than doubled between 2013 and 2023.
- Researchers at the USC Schaeffer Center report that 340B child sites grew from 1,339 in 2010 to more than 36,000 in 2024, and that nearly two-thirds of disproportionate share hospital child sites are located in ZIP codes with median household income at least 10 percent higher than that of the parent hospital.
- An analysis of CMS change-of-ownership data found that 70.1 percent of hospital buyers between 2016 and 2024 were 340B covered entities, compared with 58.7 percent of short-term acute care hospitals generally.
- Writing in the New England Journal of Medicine, Desai and McWilliams used a regression discontinuity at the disproportionate share adjustment threshold and found 340B eligibility associated with increased hospital-physician consolidation in

hematology-oncology, and with greater hospital outpatient administration of infused drugs, without evidence of expanded care for low-income patients.

Consolidation of this kind is expensive for the patients, employers, and working families CAHC represents.

- The Department of Health and Human Services, in consultation with the Department of Justice and the Federal Trade Commission, reported in January 2025 that some studies find prices increase between 6 and 65 percent following hospital acquisitions in concentrated markets, and that prices for physicians' services increase 14 percent on average after a hospital acquires a practice.
- Inpatient hospital prices paid by private health insurance plans rose 50 percent between June 2014 and December 2024, roughly double the 25 percent increase in Medicare inpatient prices over the same period, and one or two health systems now control the entire inpatient hospital market in nearly half of all metropolitan areas.
- The National Alliance of Healthcare Purchaser Coalitions found that large 340B hospitals charge 7 percent higher commercial prices than comparable non-340B hospitals and 20 percent more for outpatient procedures. It estimates the cost to employers at roughly $36 billion annually.

These costs are passed through in premiums and cost sharing and paid by the very consumers the program was designed to help. As I testified to the HELP Committee on December 3, 2025, 340B, provider market consolidation and market power is making coverage far less affordable.

Addressing Child Sites to Lower Costs (Section 8)

Section 8 responds directly to the consolidation problem, and CAHC supports it without reservation. The bill requires that an off-campus outpatient facility appear on the covered entity's most recently filed Medicare cost report on a reimbursable line, be wholly owned by the entity, sit in a designated shortage area, furnish more than drug administration alone, and independently meet charity care and Medicaid and CHIP revenue thresholds at least equal to the greater of the parent's on-campus performance or the statewide hospital average. Section 8 makes 340B eligibility a function of what a site does rather than of who acquired it. We believe that is the right test, and it is an effective constraint on acquisition-driven program growth. We also support the draft's decision not to grandfather existing registrations. We offer three recommendations to ensure these reforms work as intended:

1. **Align the transparency thresholds in Section 6 with the eligibility requirements in Section 8.** Section 8 applies to every hospital child site regardless of the size of the parent entity, but Section 6's child-site charity care reporting begins at $1 billion in net patient revenues, and its line-item margin reporting at $200 million. A hospital below those thresholds must satisfy Section 8 without any part of the underlying demonstration becoming public. We recommend that the charity care and the Medicaid and CHIP calculations supporting each child-site certification be reported under Section 6 by every covered entity

subject to Section 8. We note that Section 6 does not currently require the Medicaid and CHIP percentage to be reported at any revenue level, which leaves one of the two Section 8 eligibility tests unverifiable from outside the agency. Entities should report the date each child site was registered and whether the site was acquired from another owner, so that the relationship between 340B participation and provider acquisition can be measured directly.

2. **Trust But Verify.** Section 8 requires the covered entity to certify compliance at registration and annually thereafter. It also requires an entity that discovers a non-qualifying purchase to disclose it and to conduct an audit supervised by the Secretary. Both mechanisms depend on the entity identifying its own violation. GAO reported in October 2025 that HRSA's audit process does not confirm that identified problems have been corrected, and that the agency insufficiently verifies hospital eligibility. With tens of thousands of child sites requiring review within 120 days of enactment, we recommend explicit authority and dedicated resources for HRSA to audit child-site eligibility on a risk-adjusted basis, independent of self-disclosure.

3. **Extend recertification to parent hospital eligibility.** The draft requires child sites to certify compliance at registration and annually thereafter, and Section 3 establishes recertification requirements for subgrantees. The draft establishes no comparable schedule for verifying that a hospital covered entity itself continues to qualify. Covered entity status relies on a threshold that hospitals have both the incentive and the means to manage, and published research finds hospitals clustering immediately above the 11.75 percent disproportionate share adjustment threshold at rates not observed among ineligible hospitals. CAHC recommends a fixed recertification schedule for hospital covered entities, with clear authority for the Secretary to remove entities that no longer qualify.

None of these changes would reduce 340B support for a genuine safety net provider. They would ensure that the program's benefit follows the patients it was created to serve, rather than the transactions that expand a hospital's market power.

Covered Entities

The scope of 340B covered entities has expanded to providers who many would consider outside the safety net. They serve wealthy communities and have significant resources. Research has found that 340B entities place child sites in areas that are wealthier, healthier, better insured. We encourage you to think more broadly about how 340B resources might be better directed to true safety net providers and low income patients.

A Single, Standardized Rebate Model (Section 2)

Section 2 of the discussion draft would allow manufacturers to choose how they make the 340B price available through one of three options: an upfront discount, a discount following submission of standardized claims data to a repository, or a retrospective rebate paid within ten days of the claim. It would also let the covered entity select its own mechanism, rather than

accept the manufacturer's selected choice, if the entity passes through all resulting discounts to its 340B patients and collects only a dispensing fee.

CAHC recommends a simpler approach. Rather than a menu of mechanisms that the covered entities and manufacturers can choose based on the data they are willing to submit, the statute should default to a single, standardized rebate model supported by uniform, claims-level data.

A single rebate model is the preferred approach for several reasons. First, it produces consistent, claims-level data that gives HRSA, manufacturers, and covered entities a shared and auditable picture of every transaction. Second, that data is the single most effective safeguard against duplicate discounts, a persistent and costly compliance problem that is very difficult to detect when claims information is fragmented across programs and mechanisms. Third, a uniform rebate model is the cleanest way to reconcile 340B with the maximum fair price obligations created by the Inflation Reduction Act, avoiding the operational conflicts that arise when a single drug is subject to overlapping and inconsistent discounting rules.

CAHC made these same points in both our September 2025 and April 2026 comments to HRSA on the 340B Rebate Model Pilot Program. We encourage you to retain the draft's important rebate safeguards, including standardized claims documentation, prompt payment of undisputed claims, a documented rationale for any denied claim, and an opportunity for review of disputes.

Ensuring 340B Discounts Reach Patients (Section 7)

We strongly support the draft's recognition that covered entities should pass 340B discounts through to the patients. We support the sliding fee scale in Section 7 and recommend that its protections apply as a baseline condition of participation for all covered entities, rather than being paired only with the mechanism election in Section 2.

This patient benefit should apply regardless of whether an entity elects to choose its own mechanism, especially if the program moves to a standardized rebate model. The core promise of 340B is that discounted drugs make care more affordable for vulnerable patients, and reforms to the law should make that promise explicit and enforceable at the point of sale. This is especially important given evidence that, under current practice, discounts rarely reach patients directly.

Strengthening the Patient Definition (Section 4)

Section 4 would establish, for the first time in statute, a definition of a 340B patient. As drafted, an individual qualifies if they received outpatient health care services at the covered entity within the preceding two years, has an auditable relationship and medical record with the entity, and received the prescription from a practitioner as a result of that service or as a result of a referral.

CAHC supports creating a clear statutory patient definition and offers two recommendations to ensure it works as intended.

First, the definition should require that the covered outpatient drug be connected to the episode of care that established the patient relationship. As written, a single qualifying visit within a two-year window could be read to sweep in prescriptions that bear no clinical relationships to the care that the covered entity actually provided.

We recommend adding language requiring that the prescription arise from, and relate to, the outpatient service furnished by the covered entity. Tying the drug to the original episode of care keeps the definition faithful to the program's purpose and closes an avenue for the kind of diversion the draft is designed to prevent.

Second, while the draft permits a qualifying prescription to arise from a referral, it does not define the term or specify the circumstances for when a referral qualifies. CAHC recommends that it define a qualifying referral. An undefined referral pathway risks reopening the issues that the new patient definition is meant to solve.

The Contract Pharmacy Framework (Section 5)

CAHC supports codifying contract pharmacy arrangements in statute only as part of comprehensive federal reform that addresses oversight and accountability gaps in the current program and ensures vulnerable patients can access discounts on 340B drugs at contract pharmacies. We appreciate the bill's guardrails, including the requirement that contract pharmacies for certain covered entities be located within the entity's service area and the cap on the number of contract pharmacies for certain hospitals.

We recommend strengthening the service area requirement so that the geographic connection includes the patient, not only the covered entity. Eligibility should depend on the combination of where the patient is located and where the covered entity is located, so that a contract pharmacy is genuinely serving the covered entity's own patient community rather than extending the program's geographic reach into areas the entity does not serve. A geographic link that connects the patient, covered entity, and contract pharmacy is a straightforward way to keep contract pharmacy activity aligned with the program's purpose and to limit diversion.

Transparency (Section 6)

CAHC supports the transparency requirements in Section 6 as meaningful, comparable, and publicly available data is the foundation of accountability, and it responds directly to well-documented concerns that covered entities have not demonstrated how 340B revenue benefits patients.

To make the program's transparency framework as complete as possible, we recommend incorporating H.R. 9504, the *Tax Exempt Hospital Transparency Act* that was passed by the House Committee on Ways and Means in July 2026, as part of your 340B bill. H.R. 9504 would require high-revenue tax-exempt hospitals to report 340B information, charity care, and community benefit.

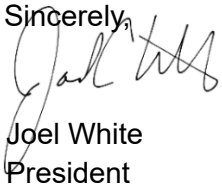
Combining these efforts would give policymakers and the public a fuller, cross-verified picture of how 340B revenue is generated and used, and would close gaps that either reporting regime would leave on its own.

Conclusion

CAHC supports reform that refocuses the out-of-control 340B program on vulnerable patients, brings transparency and accountability to how the program operates, and lowers costs for patients, employers, families, and taxpayers.

We appreciate the opportunity to comment and look forward to working with you to advance a serious, comprehensive effort to restore 340B to its original purpose.

Sincerely,



Joel White
President