ADVOCATES FOR COMMUNITY HEALTH

August 28, 2026

The Honorable Bill Cassidy, M.D.
Chairman
U.S. Senate Health, Education, Labor, and Pensions Committee
Washington, DC 20510

RE: The 340B Drug Pricing Integrity and Affordability for Patients Act

Dear Chairman Cassidy,

On behalf of Advocates for Community Health (ACH), a nonpartisan, nonprofit membership organization comprised of 55 community health center members in 22 states that serve over 4 million patients, we are writing to express our concerns with the 340B Drug Pricing Integrity and Affordability for Patients Act (340B for Patients Act) discussion draft. While ACH recognizes the importance of strengthening the 340B Drug Pricing Program, we urge you to consider modifications that preserve community health centers' ability to use the program as Congress originally intended under the law and reduce unnecessary administrative burden.

Background

Community health centers serve over 34 million patients nationwide, providing comprehensive, high-quality primary care regardless of a patient's insurance status or ability to pay. The 340B Drug Pricing Program is foundational to this mission, enabling health centers to stretch scarce federal resources by purchasing outpatient prescription drugs at discounted prices and reinvesting those savings into expanded access, comprehensive services, and care for medically underserved communities.

Health centers are responsible stewards of the 340B Program, using savings as Congress intended: to expand access to care for underserved patients and strengthen the health care safety net by stretching scarce federal resources. Forty-four of ACH's 55 members (80%) participated in an ACH survey on how 340B savings are used, and every respondent reported reinvesting 340B savings directly into patient care and community services. Specifically, members cited chronic disease prevention and management, behavioral

health services, rural access initiatives, telehealth, transportation assistance, mobile clinics, school-based health services, and other investments that improve access for medically underserved communities. These findings demonstrate that 340B savings are reinvested to sustain essential services that many health centers could not otherwise provide.

Further, Chairman Cassidy's own multi-year oversight investigation of two of the nation's largest federally qualified health centers documented how 340B savings are used to subsidize prescription medications, support patient assistance programs, expand clinical capacity, provide enabling services such as transportation and language access, and maintain compliance through robust financial oversight. While the report identified operational differences in how the two health centers administer the Program, it did not identify evidence of misuse of 340B savings by either community health center.

ACH supports efforts to strengthen the integrity and long-term sustainability of the 340B Program while preserving Congress's original intent. We believe any reforms should improve transparency and accountability through clear, practical, and consistently applied standards that demonstrate responsible stewardship of 340B resources without creating unnecessary administrative burden or diverting limited resources away from patient care. It is through this lens that we respectfully offer the following recommendations for your consideration.

Opposition to the Proposed Rebate Model

ACH strongly opposes replacing the current upfront discount model with a rebate model system. Community health centers already operate on extremely narrow margins and rely on receiving timely 340B savings to support essential services, staffing, equipment, and pharmacy operations. Requiring health centers to purchase drugs at full price and wait for reimbursement would create significant cash flow challenges while also imposing substantial administrative and technology requirements, including additional claims processing, inventory management, and compliance activities.

ACH is also concerned that requiring covered entities to pass all 340B savings directly to individual patients would fundamentally alter Congress's original intent for the Program. As discussed above, health centers reinvest 340B savings to expand access to care and provide services that are often under-reimbursed or not reimbursed at all.

Finally, the discussion draft does not explain how this requirement would work for insured patients or how it would interact with existing payer contracts, sliding fee discount programs, usual and customary pricing requirements, and other federal guidance, creating significant uncertainty for health centers. For these reasons, ACH strongly opposes the proposed rebate model and urges the Committee to remove these provisions from the discussion draft in their entirety.

Standardizing 340B Pricing Mechanisms

ACH strongly opposes the pricing structure provisions included in the discussion draft because they are necessary only to implement the proposed rebate model, which ACH believes should be removed in its entirety. Beyond our broader opposition to the rebate model, the draft also leaves significant uncertainty regarding how these pricing mechanisms would operate in practice.

As drafted, allowing manufacturers to adopt different pricing mechanisms could create a fragmented, manufacturer-specific system that would significantly increase administrative burden for community health centers. Requiring health centers to navigate different claims platforms, submission processes, timelines, and compliance requirements across manufacturers would be operationally unworkable and divert limited staff time and resources away from patient care.

More fundamentally, the proposal would place nearly all of the financial and operational risk on community health centers while giving large pharmaceutical manufacturers even greater control over how and when 340B discounts are provided. Manufacturers have substantially more financial resources, legal capacity, technical infrastructure, and negotiating leverage than individual health centers. Allowing each manufacturer to design and administer its own system would further tilt an already uneven playing field.

The result would be a David-and-Goliath dynamic in which small safety-net providers must comply with a patchwork of manufacturer-imposed requirements or risk delayed payments, denied claims, and significant cash-flow disruptions. Health centers operate on narrow margins and cannot absorb prolonged delays in accessing 340B savings. A workable policy should not allow powerful manufacturers to shift their administrative costs and financial risk onto the providers caring for the nation’s most underserved communities.

If the Committee still continues to pursue these provisions, the legislation should require a single standardized claims platform with uniform submission requirements across all participating manufacturers, require each manufacturer to use a single pricing model across all covered outpatient drugs, and clearly define whether manufacturers or covered entities determine which pricing model applies to ensure consistent implementation across the program. A neutral, HHS-operated claims clearinghouse through which covered entities submit standardized claims data would provide a centralized mechanism to prevent duplicate discounts, maintain HHS as the ultimate arbiter of 340B eligibility, and significantly reduce administrative burden by eliminating inconsistent manufacturer requirements. This approach builds on existing models, including CMS's claims data repository used for Inflation Reduction Act rebates and Oregon's Medicaid duplicate discount system, demonstrating that a centralized claims clearinghouse is both feasible and effective.

Refining the Patient Definition

ACH supports the legislation's goal of establishing greater statutory clarity around the definition of an eligible 340B patient. However, ACH recommends extending the proposed patient lookback period from 24 months to 36 months to better align with current health center patient engagement practices.

The legislation should also provide more clarity regarding referral prescriptions. While the proposed patient definition recognizes prescriptions issued "as a result of a referral," the legislation does not clearly define which referral arrangements qualify or how these provisions should operate in practice. The legislation should clearly define eligible referral relationships and establish workable documentation requirements that preserve health centers' ability to provide coordinated and continuous care.

Aligning Oversight & Reporting Requirements

ACH supports appropriate oversight, transparency, and accountability within the 340B Program and recognizes the importance of maintaining program integrity. Community health centers already participate in robust annual registration, recertification, and reporting processes through HRSA, and many of the proposed compliance requirements could be implemented within those existing frameworks. Therefore, the legislation should avoid creating duplicative reporting and additional compliance activities that increase administrative burden for health centers. Any new registration or recertification

requirements should be aligned with existing HRSA processes to streamline implementation and minimize administrative complexity.

ACH also supports reasonable transparency regarding the use of 340B savings. Again, health centers already collect and report substantial financial and operational data. The legislation should prioritize practical reporting requirements that demonstrate responsible stewardship of 340B resources while preserving health centers' flexibility to reinvest savings into patient needs.

Clarifying Contract Pharmacy Provisions

The discussion draft would establish new statutory requirements governing contract pharmacy arrangements, including requiring that prescriptions dispensed through contract pharmacies fall "within the scope" of a covered entity's qualifying grant or statutory authority, generally limiting contract pharmacies to those located within a covered entity's service area (subject to certain exceptions), and creating new standards related to duplicate discounts, audits, and compliance. While ACH supports efforts to strengthen program integrity, several of these provisions would benefit from additional clarification to ensure they can be implemented consistently without unintentionally limiting patient access.

Specifically, the legislation should clarify how the proposed "within the scope" requirement applies to referral prescriptions. As drafted, it is unclear which referral arrangements would qualify under this standard, creating uncertainty for community health centers that routinely coordinate care with outside providers. ACH also encourages reconsideration of the proposed service-area limitations, which could reduce patient access to specialty pharmacies and limited-distribution medications that are often unavailable within a health center's service area. Finally, the legislation should provide greater clarity regarding the proposed duplicate discount requirements and audit expectations, so health centers have clear, consistent compliance standards.

As Congress continues to examine and reform the 340B Program, ACH remains committed to working with lawmakers and stakeholders to ensure the program continues to support community health centers and the patients they serve.

Thank you for your consideration of these comments. We welcome discussion of these comments and direct you to contact me and/or Stephanie Krenrich, Senior Vice President of Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org for additional information.

Sincerely,

Amanda Pears Kelly
Chief Executive Officer
Advocates for Community Health