AIMED ALLIANCE

August 27, 2026

Via Electronic Correspondence

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

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

Dear Chairman Cassidy:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate your continued commitment to ensuring that the 340B Program operates with integrity and accountability so that it continues to serve the patient community as intended. Aimed Alliance is writing to provide feedback on the 340B Drug Pricing Integrity and Affordability for Patients Act discussion draft, specifically provisions codifying a patient definition, strengthening contract pharmacy oversight, and enhancing transparency and accountability. While the discussion draft takes important steps to improve program integrity and ensure that 340B benefits are directed to eligible patients, we respectfully urge the Committee to consider several recommendations to further strengthen the proposed legislation.

I. Codifying a Clear and Consistent Patient Definition

In 1996, HRSA issued guidance providing that a 340B patient is an individual with an established relationship with the covered entity, whose care is documented by the entity, who receives services from the entity or providers for whom the entity retains responsibility, and whose services fall within the scope of the entity's federally supported activities. This overly broad interpretation is inconsistent with the statute, has led to widespread ambiguity and enabled expansion beyond the program's intended safety-net entities. Aimed Alliance supports the bill's effort to codify a clear patient definition by requiring that an individual has received an outpatient health care service from the covered entity within the preceding two years, maintain an ongoing relationship with the covered entity demonstrated by auditable medical records, and receive a prescription or order for a covered outpatient drug that is connected to the care provided by the covered entity or an eligible referral. These requirements would provide greater consistency and improve program integrity.

II. Strengthening Contract Pharmacy Oversight, Compliance, and Accountability

Contract pharmacies have expanded dramatically over the past decade, growing beyond the program's original scope and creating significant challenges for oversight and compliance. This rapid growth has increased the risk of program abuses, including duplicate discounts and drug

diversion, while limiting transparency into how 340B savings are generated and used. Aimed Alliance supports comprehensive guardrails to address unregulated contract pharmacy practices and restore the integrity of the program, while ensuring that patients maintain access to needed medications.

Section 5 requires covered entities to ensure that 340B drug purchases through contract pharmacies remain within the scope of an entity's qualifying federal grant or statute, establish formal compliance procedures, and register and annually recertify contract pharmacies with the Department of Health and Human Services (HHS). Placing limitations on contract pharmacy locations, such as service area requirements and caps on the number of contracting pharmacies, may help strengthen oversight, reinforce the connection between covered entities and the communities they serve, and reduce opportunities for program abuse.

At the same time, Congress should ensure that these safeguards do not inadvertently restrict patient access to medically necessary medications. While service area requirements provide a clear and objective framework, patient referral patterns and specialty care delivery networks do not always align with geographic boundaries. As a result, individuals receiving care from regional referral centers, oncology clinics, and other specialty practices may rely on pharmacies located outside the covered entity's service area. Accordingly, Congress should consider limited exceptions for specialty pharmacies or other circumstances where access to necessary medications may be compromised, such as when patients living in rural or underserved communities must travel significant distances to receive specialized care and rely on pharmacies closer to home to access and maintain their treatment.

Requiring written agreements to be submitted to the Secretary, alongside meaningful statutory penalties for non-compliant contract pharmacies, will help ensure that all participants are held to enforceable standards. Together, these measures would promote greater accountability, while preserving access to care for patients who depend on the 340B program.

III. Enhancing Transparency and Accountability for Hospital Covered Entities

Public and stakeholder trust in the 340B Program requires transparency regarding who receives 340B discounts, how savings are used, and how safety-net services are delivered to communities. Aimed Alliance supports requiring certain hospital covered entities to annually report critical operational data, including the total number and types of individuals who received 340B drugs, total incurred costs, charity care provided, and the margins generated from covered outpatient drugs. Requiring the Secretary to annually publish this data will help provide policymakers, stakeholders, and the public with the transparency necessary to evaluate whether 340B savings are fulfilling their intended safety-net mission. Greater visibility into charity care and revenue margins will also help ensure that covered entities remain accountable to the communities they serve.

However, to ensure these reporting requirements are followed up on, Congress must also ensure federal agencies are adequately staffed to review data, identify compliance challenges, and exercise enforcement discretion. Reporting requirements without adequate staffing resources can perpetuate the existing challenges within the 340B Program. This need is particularly relevant in light of recent reductions in the federal workforce, which may further strain agencies already

tasked with overseeing complex programs such as 340B. Without sufficient staffing and resources, new reporting mandates risk generating data that cannot be effectively analyzed or acted upon. Therefore, Aimed Alliance urges future versions of this legislation to include funding and staffing support necessary to implement, monitor, and enforce these transparency requirements.

IV. Conclusion

Aimed Alliance commends the Chairman for his persistent efforts to restore integrity to the 340B Program and appreciates the opportunity to provide feedback into the proposed reforms. We respectfully urge Congress to advance the 340B Drug Pricing Integrity and Affordability for Patients Act.

If you have any questions or wish to discuss these matters further, please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney