AIMED ALLIANCE

September 2, 2026

Senator Jerry Moran
Dirksen Senate Office Building, Room 521
Washington, DC 20510

Senator Shelley Moore Capito
170 Russell Senate Office Building
Washington, DC 20510

Senator Tammy Baldwin
141 Hart Senate Office Building
Washington, DC 20510

Senator Tim Kaine
231 Russell Senate Office Building
Washington, DC 20510

Senator John Boozman
555 Dirksen Senate Office Building
Washington DC 20510

Senator John Hickenlooper
Hart Senate Office Building, Suite SH-316
Washington, DC 20510

Via Electronic Correspondence

RE: Support for the SUSTAIN 340B Act

Dear Members of the Senate 340B Bipartisan Working Group:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. Aimed Alliance applauds the 340B Working Group's commitment to ensuring the 340B Drug Pricing Program serves patients as intended. Aimed Alliance supports the SUSTAIN 340B Act, which aims to strengthen program integrity, improve transparency, and promote accountability within the 340B Program while preserving access to care for patients who rely on safety-net providers.

I. Strengthening Contract Pharmacy Oversight, Compliance, and Accountability

When Congress enacted the 340B Program, it envisioned covered entities dispensing discounted drugs through their own in-house pharmacies. In 1996, however, HRSA issued guidance permitting entities without in-house pharmacies to contract with a single outside pharmacy to dispense 340B drugs. This expansion was intended to ensure eligible covered entities were not penalized for not having an in-house pharmacy.

However, in 2010, HRSA expanded that guidance to allow covered entities to use an unlimited number of contract pharmacies to dispense 340B drugs, without geographic restrictions. As a result, the use of contract pharmacies has expanded dramatically over the past decade, growing beyond the program's original purpose of serving as a substitute for an entity's in-house pharmacy. This expansion has enabled entities to generate revenue from discounted drugs dispensed to individuals who may have only limited connections to the entity, rather than patients receiving care directly from the covered entity. This rapid growth has also created significant oversight and compliance challenges, increasing the risk of program abuse, including duplicate discounts and drug diversion, while reducing transparency into how 340B savings are generated and used.

Duplicate discounts are particularly problematic because they occur when a manufacturer provides both a 340B discount and a Medicaid drug rebate for the same prescription, resulting in two statutory discounts on a single drug. When duplicate discounts are not properly identified and prevented, state Medicaid programs may fail to collect rebates on eligible claims or may improperly seek rebates on 340B-discounted drugs. As a result, states and taxpayers may face higher costs due to forgone rebates. Aimed Alliance supports comprehensive guardrails to restrict unregulated contract pharmacy practices, prevent duplicate discounts, and restore the integrity of the program while ensuring that patients maintain access to needed medications.

Section 3 of the SUSTAIN 340B Act would strengthen oversight of contract pharmacy arrangements through registration requirements, annual recertification, standardized written agreements, contract review processes, enhanced auditing authority, and record retention requirements. The section would also increase transparency by requiring public reporting on contract pharmacy arrangements, including participating covered entities, pharmacy locations, dispensing volume, and mail-order status, providing stakeholders with greater visibility into the scope and operation of the program. Aimed Alliance supports these measures as they establish safeguards that promote compliance, accountability, and transparency.

Aimed Alliance also supports the bill's grant of authority to the Secretary to establish standards governing contract pharmacy audits. Together with the enhanced oversight and reporting provisions, this approach would provide a flexible framework to improve accountability and program integrity without imposing arbitrary caps or geographic restrictions that may not reflect patient referral patterns, specialty care networks, or the realities of accessing care.

II. 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 broad interpretation is inconsistent with the statute and has led to a rapid expansion beyond the program's intended safety-net purpose. 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.

III. Strengthening Covered Entity and Child Site Registration, Eligibility, and Accountability

The 340B Program has experienced significant growth over the years, including a substantial increase in the number of child sites, such as satellite clinics, off-site outpatient facilities, hospital departments, and other locations affiliated with a participating 340B parent hospital. These sites are eligible to participate in the program through their relationship with a covered entity. However, current eligibility standards provide limited assurance that a "child site" is meaningfully integrated

with its covered entity, such as shared policies, governance, oversight, records, and provider relationships.

Aimed Alliance supports the bill's provisions establishing a more rigorous eligibility standard that requires child sites to be wholly owned by and clinically and financially integrated with the covered entity. These safeguards would help ensure that child-site participation remains appropriately connected to the covered entity and the patient populations the 340B Program is intended to serve.

IV. Enhancing Transparency and Reporting of 340B Program Savings

Although the 340B Program has grown significantly in size and scope, there is limited publicly available information regarding how covered entities use the savings generated through participation in the program. Greater transparency is needed to demonstrate the value of the program and strengthen public confidence that savings are being used to benefit patients and communities.

Aimed Alliance supports the bill's reporting requirements, which would provide important information regarding patient populations served, charity care, and the ways in which 340B savings are used to benefit patients and the communities served by the covered entity. Transparent reporting promotes accountability while helping policymakers assess whether the program is fulfilling its intended purpose. For example, in 2023, Minnesota became the first state to require 340B financial reporting to increase transparency into the program. The state's second annual report found that covered entities generated at least $1.34 billion in net 340B revenue in 2024, more than double the $630 million reported in 2023. More than 80% of the revenue was generated by the state's largest 340B hospitals, and the report noted that the $1.34 billion figure may still understate the program's true size.[i]

While these reporting requirements, along with the requirement that covered entities attest that 340B savings are being used to benefit patients and the communities they serve, are important steps forward, the legislation could be strengthened by establishing clearer parameters for the use of 340B-generated savings. Specifically, Congress should consider establishing explicit prohibitions on the use of 340B Program funds for purposes unrelated to patient care, community benefit activities, or the covered entity's safety-net mission, including a defined list of expenditures that are not permissible uses of program-generated savings, such as annual bonuses for hospital executives. Such guardrails would help ensure that 340B savings are directed toward improving access to care, reducing barriers for vulnerable patients, and supporting the program's intended purpose.

V. Strengthening Program Integrity Through Enhanced Audits and Compliance Oversight

Current oversight mechanisms may not always be sufficient to identify and address issues such as diversion,[ii] duplicate discounts, improper eligibility determinations, or inaccurate ceiling prices. For example, HRSA audits rely heavily on self-attestation, lack standardized methods for assessing the scope of noncompliance, and may be closed without verification of corrective actions. This audit process has led to inconsistent and incomplete oversight, allowing covered entities with

identified violations to continue noncompliant practices without implementing adequate corrections.

Aimed Alliance supports the bill's enhanced audit authorities for both covered entities and manufacturers. The bill appropriately grants authority to investigate issues such as diversion, duplicate discounts, improper eligibility determinations, and inaccurate ceiling prices. We also support the requirement that corrective action plans be fully implemented before audits are closed and increasing the frequency of audits for entities found to violate requirements. These provisions help promote accountability and ensure that identified compliance issues are appropriately corrected.

VI. Preventing Duplicate Discounts Through Improved Data Sharing and Accountability

Duplicate discounts occur when a manufacturer provides a 340B discount on a drug and is also required to pay a Medicaid rebate on the same unit of medication. Currently, HRSA's oversight of duplicate discounts is limited to Medicaid fee-for-service, and does not extend to Medicaid managed care, where most 340B utilization occurs. In addition, HRSA does not require repayment for violations or assess whether state Medicaid policies contribute to duplicate discounts.

Aimed Alliance supports the creation of an independent 340B data clearinghouse to facilitate accurate claims tracking and identification of potential duplicate discounts. We also support the required repayment of identified duplicate discounts for 340B drugs that occur in both State Medicaid fee-for-service and managed care programs. By improving data sharing and increasing accountability, the clearinghouse would help ensure compliance, reduce administrative uncertainty for stakeholders, and ensure that state Medicaid programs can recover rebates to which they are entitled, helping address state health care costs.

VII. Conclusion

Aimed Alliance commends the 340B Bipartisan Working Group for its efforts to restore integrity to the 340B Program. We urge Congress to advance the SUSTAIN 340B Act to strengthen oversight, improve transparency, reduce opportunities for diversion and duplicate discounts, and establish clearer standards for participation in the 340B Program.

We appreciate your consideration. We look forward to working with Congress to support a stronger and more sustainable 340B Program.

Sincerely,

Olivia Backhaus
Staff Attorney
Aimed Alliance

[i] Minn. Dep't of Health, 340B Covered Entity Report: Report to the Legislature, 2025 (Feb. 27, 2026), https://www.health.state.mn.us/data/340b/docs/2025report.pdf.

[ii] Diversion occurs when drugs purchased at 340B prices are sold or otherwise transferred to individuals who are not patients of the covered entity.