March 28, 2024

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
709 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Submitted electronically to: bipartisan340BRFI@email.senate.gov

RE: Comments on the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN 340B Act)

Dear Senators Thune, Capito, Moran, Stabenow, Baldwin, and Cardin:

Premier Inc. is grateful for your continued leadership and bipartisan support of the 340B Drug Discount Program and for the enduring mission of the 340B Program to enable safety net healthcare providers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Premier thanks you for the opportunity to provide comments to the discussion draft of the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN 340B Act) issued on February 2, 2024, as well as your requests for information (RFI) relating to the discussion draft.

These comments follow Premier's response to your initial RFI relating to the 340B Program, which we submitted on July 26, 2023 (initial response).[1] Premier appreciates that several of our recommendations from the initial response have been incorporated in the SUSTAIN 340B Act draft. Premier hopes that the below responses to the SUSTAIN 340B Act and RFI are helpful to you as you continue work to improve the 340B program.

I. BACKGROUND ON PREMIER INC.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,350 U.S. hospitals and approximately 300,000 continuum of care providers to transform healthcare. Premier's sophisticated technology systems contain robust standardized data gleaned from 45 percent of U.S. hospital discharges, 2.7 billion hospital outpatient and clinic encounters and 177 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier is also a leader in identifying, fulfilling and closing gaps in diverse sources for critical product categories, a strategy that proved to be critical as the country looked to increase domestic manufacturing and identify new sources of critical supplies.

[1] Premier response to 340B Drug Discount Program Request for Information. July 26, 2023. Available at: https://premierinc.com/downloads/Premier-Comments_Congressional-RFI-on-340B_July-2023_FINAL.pdf

A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government, and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare and ensuring healthcare providers have access to the right supplies, at the right time, to treat patients.

II. FEEDBACK ON SECTIONS OF THE DRAFT LEGISLATION

Section 3: Contract Pharmacies

Premier is encouraged that the SUSTAIN 340B Act adopts our recommendation from our initial response and clearly codifies that covered entities may dispense covered outpatient drugs through contract pharmacies, and requires manufacturers to offer each covered outpatient drugs for purchase at or below the applicable ceiling price regardless of when a covered outpatient drug is dispensed through a contract pharmacy. Similarly, Premier also appreciates that the SUSTAIN 340B Act incorporated another recommendation from our initial response to require civil monetary penalties for drug manufacturers that refuse to offer, sell or deliver eligible 340B drugs. Ensuring manufacturer delivery of covered outpatient drugs to contract pharmacy locations will directly address manufacturers' unlawful restrictions on 340B drug access when dispensing through contract pharmacies. ***To further clarify manufacturers' obligations, Premier recommends revising subsection (A) of the proposed 42 U.S.C. 256b(a)(11) to indicate that the requirement to extend 340B pricing to contract pharmacy dispensed covered outpatient drugs applies to all covered outpatient drugs subject to an agreement with the Secretary under paragraph (1), including limited distribution drugs with the exception of those that are limited distribution due to Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS) requirements.***

At the same time, Premier is concerned that the registration and contract review requirements proposed in the SUSTAIN 340B Act may be unnecessary in light of existing contract pharmacy registration requirements and the improvements in contract pharmacy arrangement integrity proposed in the SUSTAIN 340B Act. The existing OPAIS registration process has proven effective for ensuring transparency in covered entity contract pharmacy arrangements. The SUSTAIN 340B Act's proposal for review of all contract pharmacy agreements would create significant administrative burdens for the Health Resources and Services Administration (HRSA) and covered entities while likely delaying the ability of covered entities to participate in contract pharmacy arrangements. This process may divert resources away from covered entities without a corresponding program integrity benefit. ***Accordingly, Premier recommends deleting subsections (B) and (C) of the proposed 42 U.S.C. 256b(a)(11).***

Premier supports the SUSTAIN 340B Act's proposal to develop standard contract provisions required for contract pharmacy agreements. Doing so will clarify the obligations of both contract pharmacies and covered entities. However, Premier is concerned that large pharmacy chains have begun requiring covered entities to contract with all pharmacies affiliated with the chain, when doing so is unnecessary to treat the geographical needs of a covered entity's patients. ***Premier recommends adding to the list of required contract pharmacy provisions set forth in subsection (ii) of the proposed 42 U.S.C. 256b(a)(11)(D) that contract pharmacies cannot discriminate against covered entities that are unwilling to enter into contract pharmacy arrangements with pharmacies that are not expected to provide meaningful pharmacy services to the covered entities' patients.***

Premier is also concerned that the SUSTAIN 340B Act proposes requiring covered entities to extend their financial assistance programs to dispensing by contract pharmacies. The operational logistics of contract pharmacies extending such programs at the time of dispense at a contract pharmacy raises a host of technical and operational challenges that require extensive consideration and study before such a requirement should be imposed. ***For this reason, Premier recommends delaying the effective date of***

such a provision for two years following the enactment of the SUSTAIN 340B Act and a requirement that HRSA implement the requirement through notice and comment rulemaking to ensure operational challenges and limitations are fully addressed.

Finally, in response to the RFI's inquiries relating to contract pharmacies, Premier does not believe that imposing geographic or other restrictions on the use of contract pharmacies is consistent with the intent of the 340B Program or necessary for 340B Program integrity. Limiting the pharmacies with which a covered entity can contract to dispense 340B drugs will reduce covered entities' access to the benefits of the 340B Program and covered entities' ability to stretch scarce federal resources. The contract pharmacy program integrity provisions proposed in the SUSTAIN 340B Act and elsewhere in the 340B Statute provide a comprehensive regulatory oversight framework for contract pharmacies, and limitations on particular contract pharmacy arrangements (whether geographic or otherwise) would not provide meaningful incremental program integrity support. ***Accordingly, Premier recommends maintaining the SUSTAIN 340B Act as currently drafted in this regard.***

Section 4: Patient Definition

Premier agrees with the RFI that there has been uncertainty in the administration of the 340B Program with respect to the definition of "patient," but Premier believes this uncertainty is the result of administrative missteps by HRSA, as opposed to a structural problem with the 340B Statute or HRSA's 1996 definition of "patient."[2] As the U.S. District Court for the District of South Carolina remarked in *Genesis Health Care, Inc. v. Becerra*, HRSA has attempted to interpret the term "patient" in a way "contrary to the plain language of the 340B statute," HRSA "does not appear to have made any attempt to consider the purpose of the 340B Statute" in interpreting the term "patient," and that HRSA's approach to interpreting "patient" "demonstrates a lack of consistency."[3] The uncertainty in the administration of the 340B Program relating to the definition of "patient" has been due to HRSA's inability to hew to the patient definition it established for itself in its 1996 guidance document.

Accordingly, Premier does not believe restrictions beyond those set forth in the 1996 HRSA guidance are warranted, nor would restrictions be consistent with the intent of the 340B Program in that they would reduce access to 340B drugs for both patients and covered entities. Further defining "patient" for purposes of 340B drug purchasing in a way that would misalign the definition with covered entities' own definitions of patient for admission and registration purposes would also create significant confusion for covered entities and patients. For that reason, the 1996 definition provides appropriate flexibility but also accountability through auditable records, and further restricting patients of the covered entity would be problematic. ***Premier recommends that the SUSTAIN 340B Act either not codify a definition of "patient" or codify HRSA's 1996 patient definition.***

Section 6: Transparency

In general, Premier is a proponent for transparency and believes that all entities within the healthcare ecosystem should strive to be transparent. At the same time, Premier believe that transparency standards must be implemented in a manner that supports their intended purpose and provides value to patients, providers, and the government.

With that being said, it is unclear to us how the proposed subsection (5) of subsection 42 U.S.C. 256b(d), "Reporting of Program Savings," furthers the 340B Program's goal of helping covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Complex reporting requirements can require significant technology, consultant, and personnel expenses that can negate the savings received from the 340B Program and take away from the ability to serve patients and use savings for patient care. Moreover, many 340B-participating covered entities are required to meet extensive reporting requirements in conjunction with their qualifying status to

[2] 61 Fed. Reg. 55156 (Oct. 24, 1996).
[3] *Genesis Health Care, Inc. v. Becerra*, 2023 WL 7549156 (S.D. N.C. 2023).

participate in the 340B Program. The elements to be reported under the "Reporting of Program Savings" section are extensive and extend far beyond reporting program savings and how those savings are used.

The data points that would be required to be disclosed under this section appear to be intended to enable analytical comparisons amongst covered entities. Premier strongly cautions that comparisons based on this information may be of limited utility and potentially misleading due to the unique nature of every covered entity, the populations they serve, the services they provide, among myriad other factors that make comparisons not "apples to apples." Rather than enabling meaningful data-based comparisons among covered entities, there is the potential to create confusion and potential adverse consequences when actions are taken by individuals, entities and government agencies based on that confusion. ***Accordingly, Premier strongly recommends limiting reporting requirements to qualitative information describing covered entities' 340B savings spending.***

Section 8: Preventing Duplicate Discounts

Premier respectfully disagrees with the RFI's statement that, "as has been highlighted by [the Government Accountability Office ("GAO")][4] and the [Office of Inspector General ("OIG")],[5] duplicate discounts continue to occur in the program due to lack of a system to appropriately identify 340B claims." Neither the GAO nor the OIG identified a single duplicate discount in the cited sources. Premier is also unaware of any government findings identifying material duplicate discount violations caused by covered entities.

The SUSTAIN 340B Act proposes covered entities provide claims level data to a government contractor national clearinghouse, which the clearinghouse will then provide to manufacturers to determine units of a 340B drug that "may generate a rebate." However, the covered entity's provision of this data is duplicative of claims already submitted to the state Medicaid programs, and manufacturers would be unable to use that data to identify any actual duplicate discounts that have been paid.

To the extent that the SUSTAIN 340B Act establishes a national data clearinghouse to collect rebate and purchase data, it should use only such data as is already available to state Medicaid programs and manufacturers. State Medicaid programs hold the information as to whether a manufacturer gave a discount on a particular drug billed to a state Medicaid program and can require Medicaid managed care plans to report drugs billed to them that were purchased at a manufacturer discount. State Medicaid programs also hold the information as to whether the state Medicaid program actually obtained a rebate from the manufacturer on that particular drug. ***Accordingly, to further strengthen oversight of potential duplicate discounts, Premier recommends that any clearinghouse rely on information that is already being reported by covered entities and available from other sources.*** A new federal clearinghouse contractor is unnecessary and would create additional bureaucracy and costly administrative burdens for all 340B stakeholders.

Moreover, the requirement that covered entities repay affected manufacturers for identified duplicate discounts, without a corollary ability for covered entities to refile Medicaid claims for such drugs, would result in covered entities receiving reduced Medicaid reimbursement for drugs (typically at the 340B actual acquisition cost) when the covered entity paid the manufacturer the full cost of the drug. In other words, covered entities would incur a revenue deficit for any duplicate discounts, including any duplicate discounts that may have resulted from errors by the state Medicaid program. At the same time, the state Medicaid program would receive a rebate from the manufacturer while paying the covered entity at the reduced 340B reimbursement rate. In other words, the state Medicaid program would receive a benefit from the duplicate discount at a cost to the covered entity: a reduced reimbursement to the covered entity and a rebate from the manufacturer. ***Accordingly, Premier strongly recommends that subsection (f) of subsection 1150D of the SUSTAIN Act be revised to require state Medicaid programs to work with affected manufacturers regarding repayment of identified duplicate discounts.***

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[4] *Citing* GAO-20-212. https://www.gao.gov/assets/gao-20-212.pdf.
[5] *Citing* State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates. OIG Report (OEI-05-14-00430). 06-06-2016.

Section 5: Child Sites

Premier supports the SUSTAIN 340B Act's proposal to use the Medicare provider-based legal framework to identify child sites of a covered entity. ***However, Premier recommends incorporating that framework into the 340B Statute by reference to ensure consistency with the Medicare program and avoid confusion. Premier also recommends that the child site definition be applied across all covered entity types to ensure consistency across the 340B Program.***

Section 7: Enhancing Program Integrity

Premier agrees with the SUSTAIN 340B Act's goal of establishing consistency in the HRSA auditing program. However, to achieve this goal, it is critical for HRSA's audit standards to be established through notice and comment rulemaking. HRSA's current method of establishing audit standards through guidance has resulted in poorly developed and inconsistent audit standards in conflict with the plain meaning and intent of the 340B Statute.[6] ***Accordingly, Premier recommends revising subsection (A) of the proposed 42 U.S.C. 256b(f)(1) to require HRSA to promulgate audit standards through notice and comment rulemaking.***

Section 9: Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies

Premier supports the SUSTAIN 340B Act's prohibition on commercial third-party payors discriminating against covered entities by imposing requirements, exclusions, reimbursement terms, or other conditions on such entity because of their status as a covered entity. ***However, Premier recommends that the enforcement provisions under the SUSTAIN 340B Act apply to all commercial third-party payors to whom the requirement applies: group health plans, health insurance issuers offering group or individual health insurance coverage, or pharmacy benefit managers (PBMs).*** The discussion draft of the SUSTAIN Act provides that the enforcement mechanism would only be imposed on PBMs, and applying this enforcement mechanism to all commercial third-party payors subject to the non-discrimination requirements is essential to ensuring compliance with the requirements and the intent of the 340B Program to generate savings for covered entities.

Section 11: Studies and Reports

Premier agrees with the SUSTAIN 340B Act's proposal for the Medicaid and CHIP Payment and Access Commission (MACPAC) to study the efforts of State Medicaid agencies to prevent duplicate discounts and for HHS to study contract pharmacy dispensing fees. ***However, Premier also recommends that the SUSTAIN Act require the GAO to study and report on manufacturer compliance with the ceiling price for 340B drugs and the sufficiency of the existing authority for and conduct of oversight activities for such manufacturer compliance.***

Section 12: Additional Resources and Oversight

While Premier supports the additional oversight resources proposed in the SUSTAIN 340B Act, we are concerned that the SUSTAIN 340B Act does not establish prioritization of the uses of those resources. As Premier discussed in our initial response, since 2012, HRSA has conducted more than 1,800 audits of 340B providers and 36 audits of pharmaceutical manufacturers. This lopsided approach to 340B Program oversight is deeply concerning, and Premier is concerned that HRSA would continue to use these additional resources to audit covered entities without a corresponding focus on auditing manufacturers. ***Premier recommends that Section 12 of the SUSTAIN 340B Act be revised to require HRSA to utilize half of the appropriated resources for oversight of covered entities and half of the appropriated resources for oversight of manufacturers.***

[6] *See, e.g., Genesis*.

III. CONCLUSION

In closing, Premier supports your bipartisan mission of improving the 340B Program and looks forward to continuing to work with you to achieve the intent of the 340B Program.

If you have any questions regarding our comments, or if Premier can serve as a resource on these issues, please do not hesitate to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.