PREMIER TRANSFORMING HEALTHCARE TOGETHER®

July 26, 2023

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@mail.senate.gov and Bipartisan340BRFI@email.senate.gov

Re: 340B Drug Discount Program Request for Information

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

Premier Inc. applauds your leadership and bipartisan dedication to ensuring that the 340B Drug Discount Program (the "340B Program") continues to achieve its goal of allowing safety net healthcare providers to access discounted drug prices to enable these entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Premier further appreciates your thoughtful approach to seeking stakeholder input in the development of consensus policy proposals to further refine the 340B Program to enable healthcare providers to offer improved services and care in the communities they serve, while also improving transparency and integrity of the program.

Premier's responses to the request for information (the "RFI") reflect the concerns of our member hospitals and health systems which, as service providers, have a vested interest in the success of the 340B Program and developing potential strategies to address the unprecedented threats to the 340B Program that are arising on an almost daily basis.

I. BACKGROUND ON PREMIER INC.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,400 U.S. hospitals and approximately 250,000 continuum of care providers to transform healthcare. Premier's sophisticated technology systems contain robust data from nearly half of U.S. hospitals and 200,000 ambulatory clinicians. 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.

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

[1] H.R. Rept. No. 102-384(II), at 12 (1992).

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. BACKGROUND ON THE 340B PROGRAM

The 340B Program was established in 1992 by Congress in response to the dramatic increase in drug prices following establishment of the Medicaid Prescription Drug Rebate Program in 1990. The Drug Rebate Program requires drug manufactures to provide state Medicaid programs with rebates for covered outpatient drugs. In the two years following implementation of the Medicaid Drug Rebate Program, drug manufacturers dramatically increased drug prices to compensate for revenue lost to Medicaid drug rebates. In 1991, drug manufacturers increased prices by approximately 23%, and then by another 25% in 1992.[2] The 340B Program, established by Congress in 1992, served to protect safety net healthcare providers from these drug price increases, implemented to protect manufacturer revenue in the face of the Medicaid Drug Rebate Program.

Congress made clear in the enactment of the 340B Program that certain safety net providers should qualify for 340B discounted pricing by virtue of the critical services they provided to their underserved communities. Congress did not dictate how these organizations should use their savings. Indeed, such requirements would have been unnecessary because these safety net providers, by virtue of their safety net status, serve vital roles supporting uncompensated care and other un-/under-reimbursed services in their communities. Establishing specific requirements for the use or disclosure of revenue (beyond those otherwise required under the myriad of federal and state laws already in place) would have been not only unnecessary, but such requirements would have placed new administrative burdens on these safety net providers, further consuming the scarce resources of the provider in opposition to the purpose of the 340B Program. These same considerations still exist today.

Premier acknowledges the RFI's request for information on ways to improve accountability of covered entities and to ensure appropriate transparency, but we would urge you to consider whether covered entity accountability and transparency are legitimate and material concerns in the 340B Program. Covered entities are already subject to extensive accountability and transparency requirements. In 2022, the Health Resources and Services Administration ("HRSA") audited almost 200 covered entities for compliance with 340B Program,[3] while it audited only five (5) drug manufacturers in the same year.[4] Moreover, many 340B-participating covered entities are required to meet extensive reporting requirements in conjunction with their qualifying status to participate in the 340B Program.[5] Drug manufacturers are not required to meet any such transparency requirements.

Premier also acknowledges the RFI's statement that both covered entities and manufacturers are frustrated that duplicate discounts continue to occur, but we would also question whether duplicate discounts are a material compliance concern in the 340B Program. Through the Medicaid Exclusion File and state Medicaid program billing requirements, both HRSA and state Medicaid programs have implemented successful procedures to prevent duplicate discounts in Medicaid Fee for Service claims. Premier is not aware of any evidence suggesting there is a systemic duplicate discount problem as to Medicaid Fee for Service claims that poses a meaningful concern to the integrity of the program. As to Medicaid managed care claims, any duplicate discount concerns should be taken up with the Centers for Medicare and Medicaid Services ("CMS"), the state Medicaid programs and the Medicaid plans, and any new policies should not inhibit

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[2] *See, e.g.*, Health Care Finance Review, Vol 25, Iss. 3, 5-23 (2004) (citing data from the Centers for Medicare and Medicaid Services), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194863/ (last visited July 18, 2023).
[3] *See* HRSA, *Program Integrity: FY22 Audit Results*, https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results (July 7, 2023) (last accessed July 19, 2023).
[4] *See* HRSA, *FY 2022 Manufacturer Audit Results*, https://www.hrsa.gov/opa/program-integrity/fy-22-manufacturer-audit-results (Dec. 21, 2022) (last accessed July 19, 2023).
[5] *See, e.g.*, HRSA, *Health Center Program Uniform Data System (UDS) Data*, https://data.hrsa.gov/tools/data-reporting (last visited July 19, 2023).

covered entities' ability to access 340B pricing on drugs reimbursed by Medicaid managed care plans. CMS has acknowledged in rulemaking materials that there are not currently processes and requirements in place as to parties other than covered entities that are necessary to address identification and prevention of duplicate discounts as to Medicaid managed care claims.[6]

At the same time, manufacturer restrictions on purchasing of drugs at 340B discounts pose an existential threat to the 340B Program. These restrictions are not only flagrant violations of the 340B Statute, but they also fly in the face of Congress' intent to allow safety net providers to access discounted drug prices. ***In the RFI's spirit of addressing the true threats to the 340B Program's stability, Premier urges the Senate to recalibrate its focus onto policy solutions to these manufacturer actions that pose a significant and widespread threat to the stability and success of the 340B Program.***

III. RESPONSES TO THE QUESTIONS POSED IN THE RFI

1. *What specific policies should be considered to ensure HRSA can oversee the 340B Program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B Program?*

   Premier has concerns that the Health Resources and Services Administration ("HRSA") tends to leverage sub-regulatory guidance and/or Frequently Asked Questions ("FAQs") to enforce the 340B Program which can be changed overnight with little to no notice, making it difficult for covered entities to be aware of changes or provide timely feedback. Therefore, ***Premier urges Congress to ensure that HRSA has the necessary rulemaking authority to develop, oversee and enforce the rules of the 340B Program.*** Premier believes that a proper notice and comment rulemaking process would allow the public and 340B stakeholders to bring important considerations to HRSA's attention and to strengthen HRSA's administration of the 340B Program. Rulemaking authority could provide greater stability to the 340B Program by allowing for the establishment of clear, legally enforceable standards relating to the use of contract pharmacies, the scope of covered entities eligible to participate in the 340B Program, and which individuals may be considered patients of a covered entity.

   Premier also believes it is equally important for HRSA to have sufficient resources and authority to properly administer the program, but also for HRSA to efficiently utilize its resources for the betterment of the 340B Program. For example, devoting resources to auditing almost 200 covered entities in 2022 while auditing only five manufacturers in the same time period would not appear to be the most appropriate or equitable use of HRSA's resources. This is further exemplified by the continued and increasing instances of manufacturer violations of the 340B Ceiling Price Rule.[7] Finally, this is also exemplified by HRSA's frequent delegation of its enforcement discretion to the 340B Program Prime Vendor, further demonstrating that HRSA is not sufficiently resourced, or does not have the necessary expertise, to properly administer the program on its own.

2. *What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?*

   An increasing number of drug manufacturers are violating federal law by imposing restrictions on 340B drug sales, including (as of the date of this letter) 24 manufacturers restricting access to 340B pricing on drugs dispensed through contract pharmacies. These actions significantly harm patients and strip hospitals participating in the 340B program of funds that could be used to support patient and community programs at a time in which hospitals are reeling from the COVID-19 pandemic, facing severe labor shortages, grappling with inflation, and struggling with supply chain problems.

[6] 88 Fed. Reg. 34238, 34246 (May 25, 2023).
[7] 83 Fed. Reg. 55135 (Nov. 2, 2018); HRSA, *Program Integrity*, https://www.hrsa.gov/opa/program-integrity (July 2023), last visited July 20, 2023 (citing manufacturer violations).

Both previous and the current Administrations have maintained that these drug manufacturer actions violate federal law, and many members of Congress have voiced opposition to these actions. Due to on-going litigation and the interpretation of the 340B statute by certain federal courts, these manufacturer restrictions have continued to increase and are expected to become increasingly common. 340B Health conducted an analysis using HRSA data and found that as of June 1, 2023, the contract pharmacy restrictions imposed by drug manufacturers are stripping the hospital safety net of $8.4 billion annually in savings intended for use by safety net providers.[8]

Contract pharmacy arrangements allow covered entities to extend the value of the 340B program, as allowed by law, which is in turn used to provide and maintain access to healthcare programs that might not otherwise exist and likely could not be maintained but for the benefits obtained through contract pharmacy arrangements. Loss of these benefits can be devasting for healthcare safety net providers, and the patients they serve.

Specifically, Premier urges Congress to:

- ***Act to clarify that unilateral drug company restrictions on access to 340B pricing are unlawful;***
- ***Clarify that 340B covered entities and their contracted pharmacies can access limited distribution drugs from manufacturers;***
- ***Prohibit retail and chain pharmacies from requiring that all pharmacies within the parent company be added as a contract pharmacy when not necessary to treat the geographical needs of a covered entities patients; and***
- ***Require the Department of Health and Human Services (HHS) to impose civil monetary penalties on drug manufacturers that refuse to offer, sell, or deliver eligible 340B drugs.***

3. *What specific policies should be considered to ensure that the benefits of the 340B Program accrue to covered entities for the benefit of patients they serve, not other parties?*

Premier encourages Congress to act to prevent manufactures, health insurers, and pharmacy benefit managers ("PBMs") from taking savings generated from participation in the 340B Program away from covered entities and the care provided for their patients. For example, health insurers and PBMs are implementing discriminatory policies that harm 340B providers, such as by paying less for 340B drugs than they pay for non-340B drugs or requiring burdensome identification of 340B claims. These actions undermine the healthcare safety net by reducing the 340B savings that Congress intended for providers and interfering with provider access to the 340B Program. ***Premier encourages Congress to prohibit discriminatory actions against 340B providers and pharmacy partners by a PBM, group health plan, health insurance issuer offering group or individual health insurance, or sponsor of a Medicare Part D prescription drug plan based on the providers' status as 340B entities and authorize civil monetary penalties against PBMs or insurers that implement discriminatory policies.*** The 340B Program is intended to allow participating entities to support patient care services, not financially benefit for-profit insurers.

Additionally, as mentioned in above in response to question two, manufacturers are imposing restrictions on sales of 340B drugs and are expected to continue to impose increasingly draconian restrictions. These restrictions are taking money away from covered entities and the patients they serve and putting it directly in the pockets of manufacturers, who generate billions of dollars in profit without any obligations or restrictions on how these profits are used. As noted above in more detail, Premier believes that Congress needs to act to prevent these discriminatory practices.

[8] 340B Health, *Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals*, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf (July 2023), last visited July 20, 2023.

4. *What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?*

   Premier believes the program as currently structured appropriately allows for covered entities to prevent and identify duplicate discounts as to Medicaid Fee for Service. Premier does not believe additional polices imposed on covered entities would provide additional benefit and could result in imposing onerous administrative obligations, reducing the 340B Program benefit available to support patient care and communities.

   Further, any policies or requirements intended to address Medicaid Managed Care duplicate discounts should be directed at CMS, state Medicaid Programs and Medicaid plans and not place burden covered entities. For example, the implementation of a standardized process across states for identification of 340B drugs, including required use of the Medicaid Exclusion Files from HRSA, could be helpful.

5. *What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B Program and give healthcare stakeholders greater confidence in its oversight?*

   Premier believes that the 340B statute currently provides for the necessary and appropriate oversight of covered entity compliance. However, manufacturers are not following program rules and need additional program integrity measures that will improve the accountability of the 340B program. ***Premier urges Congress to take actions to prevent manufacturers from imposing any restrictions on access to 340B pricing. Further, Premier encourages Congress to require HRSA to conduct more audits of manufacturers to ensure compliance with 340B ceiling price requirements.*** Alternatively, Congress could impose user fees on manufacturers to fund additional oversight of manufacturers. The increasing number of manufacturer ceiling price violations make clear that manufacturers need additional oversight and accountability for compliance.

6. *What specific policies should be considered to ensure transparency to show how 340B healthcare providers' savings are used to support services that benefit patients' health?*

   As discussed above, covered entities are, by definition, safety net providers with an array of existing reporting obligations. Premier cautions Congress against increased reporting requirements for covered entities. Complex reporting requirements can require significant technology, consultant, and personnel expenses that can negate the savings received from the program. Additionally, there are already many reporting requirements for covered entities, in particular hospitals, and many new reporting requirements can be duplicative of current reporting efforts. All of this takes away from the ability to serve patients and use savings for patient care.

   Covered entities also undergo substantial HRSA audits that ensure transparency in the program. HRSA requires all covered entities to be recertified each year to assure integrity, compliance, transparency, and accountability. Providers and manufacturers are also subject to audits to ensure they are in compliance with 340B program requirements, but since 2012, HRSA has conducted more than 1,800 audits of 340B providers and 36 audits of pharmaceutical manufacturers. Premier recommends that Congress require HRSA to increase the number of audits on manufacturers to ensure that manufacturers are complying with program rules and requirements.

   Should Congress wish to explore this further, Premier believes it is essential that Congress host several stakeholder roundtables to understand the potential benefit of additional reporting requirements versus the additional burden placed on safety net providers and the downstream impact to patient care.

IV. CONCLUSION

In closing, Premier appreciates and shares your bipartisan goals of improving the 340B Program. Premier looks forward to working with the Senate, under your leadership, to further refine the 340B Program to enable healthcare providers to offer improved services and care in the communities they serve, while also improving transparency and integrity of the program.

If you have any questions regarding our comments, or if Premier can serve as a resource on these issues, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

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Premier Inc.