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Submitted electronically via: Bipartisan340BRFI@email.senate.gov

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

Re: Discussion Draft of the SUSTAIN 340B Act and Supplemental Request for Information

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

Vizient, Inc. appreciates the opportunity to respond 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) (hereinafter "Discussion Draft") and supplemental request for information (RFI). We thank the Senators for their efforts to maintain, improve and expand access to healthcare services through the 340B Drug Discount Program ("340B Program"). Vizient supports efforts to protect hospitals' ability to continue to purchase prescription drugs through the 340B Program so that they can stretch scarce resources to support vital, comprehensive healthcare services for patients and communities in need.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient appreciates that certain provisions of the Discussion Draft, particularly once further refined, would be helpful to covered entities (CEs) and we thank the Senators for their inclusion. For example, the Discussion Draft protects CEs from harmful manufacturer policies (e.g. manufacturers refusing to offer or deliver 340B drugs to CEs or their contract pharmacies, placing conditions on the ability of a CE to purchase 340B drugs, and restricting distribution for only 340B drugs) and harmful payer policies (e.g. commercial payers discriminating against CEs based on the 340B Program by banning policies that would lower reimbursement for 340B drugs and require providers to identify 340B claims).

At the same time, given the complexity of the program, Vizient is cautious of legislative changes that could dilute the savings or impose burdens on CEs as this would ultimately negatively impact patient care. For example, policies that narrow how 340B Program savings could be used, such as directing them solely to the provision of pharmaceuticals to vulnerable populations, would result in fewer services being provided more broadly, including in underserved communities. As there is significant variability in how a CE may utilize the 340B Program, it is imperative that these approaches are understood in the context of potential legislative change to ensure that the 340B Program would truly be strengthened.

While Vizient responds to several provisions of the Discussion Draft and questions posed in the RFI, we emphasize that there are numerous areas of ambiguity and uncertainty which make it difficult to grasp the overall implications of the Discussion Draft. Again, given the complexity of the 340B Program and its importance to CEs and patients, we urge the Senators to ensure that any legislative changes contemplated do not disrupt the 340B Program to the detriment of CEs.

Section 3. Contract Pharmacy

Vizient appreciates the Senators' inclusion of legislative text that would help ensure CEs may continue to use contract pharmacies. Contract pharmacies play a critical role in helping CEs optimize the 340B Program, by supporting continuity of care and patient access to needed medications. However, we do have concerns that the Discussion Draft places additional, burdensome requirements on how CEs utilize contract pharmacies.

For example, the Discussion Draft provides that each CE shall annually register with the Secretary any contract with a contract pharmacy and that the Secretary would review all the written agreements between a CE and each of the contract pharmacies to ensure compliance. Vizient is concerned that this process is excessively burdensome to CEs and the Secretary because it would require the sharing of a large volume of written agreements that would already be vetted for compliance by CEs and then the Secretary would need to again review these agreements.

In addition, Vizient is concerned that the review requirement could potentially delay use of contract pharmacies since it unclear whether the Secretary would have to review each agreement before utilization of the contract pharmacy could begin. Since contract pharmacies

already need to be registered and audit processes already exist to help ensure compliance, Vizient believes the additional registration and review requirements are unnecessary and could have the unintended consequence of limiting use of contract pharmacies due to administrative challenges.

Vizient does appreciate that the Discussion Draft aims to protect the relationship between CEs and contract pharmacies, but we are concerned that future iterations of the Discussion Draft will impose limits on the number of contract pharmacies based on the questions provided in the RFI, such as those related to geographic limits, specialty pharmacies, the number of contract pharmacies a CE may contract with and differences in utilization of contract pharmacies by urban and rural hospitals.[1] Vizient notes that there is no clear policy reason to limit contract pharmacy arrangements and doing so may be detrimental. For example, limiting contract pharmacies could limit patient access to specialty medications, particularly as manufacturers control and limit access through networks. Also, hospitals often utilize contract pharmacies to improve access to care in rural areas, where patients do not live near the hospital. Vizient emphasizes the importance of flexibility regarding contract pharmacies as arbitrary restrictions will negatively impact patient care.

Lastly, the Discussion Draft would effectively impose sliding fee scales and financial assistance policies for all contract pharmacy locations. Vizient is concerned that these types of policies appear to counter the purpose of the 340B Program by directing how 340B savings should be used, while also raising questions regarding the intent of this requirements. Further, Vizient is concerned such policies would be difficult to operationalize since the 340B determination is often made after a drug is dispensed. As a result, it is unclear what operational changes would be needed to implement this section that could result in unintended consequences that are not easy to identify presently.

Section 4. Patient Definition

In the Discussion Draft, vague placeholder language[2] is provided regarding the definition of "Patient". Given this ambiguity, it is extremely difficult to review the Discussion Draft completely as the definition of patient is paramount to interpreting each section of the Discussion Draft.

In addition, the recent litigation[3] has not deterred the Health Resources and Services Administration (HRSA) from reiterating the existing 340B patient definition in compliance resources,[4] suggesting that there may not be a need to define patient in statute. In the *Genesis* case,[5] the Court found that HRSA does possess authority to implement its

[1] For example, in the RFI, Senators ask "If stakeholders are proposing additional limitations on the use of contract pharmacies, how should any restrictions reflect the difference between how urban and rural hospitals utilize contract pharmacy arrangements? If stakeholders are proposing geographic or other restrictions, please provide specific data-based suggestions and reasoning."
[2] In the Discussion Draft, the text provided for Section 4 reads as follows, "TBD/refer to explanatory document"
[3] Genesis Health Care Inc. v. Becerra, No. 04:19-CV-01531 RBG (D.S.C.) Nov.3, 2023).
[4] https://www.hrsa.gov/opa/educational-resources/patient-definition-resources
[5] https://storage.courtlistener.com/recap/gov.uscourts.scd.250571/gov.uscourts.scd.250571.143.0.pdf

interpretations of the statutory term “patient” so long as such a definition is consistent with the plain language of the statute.

RFI Question: The 340B statute does not include a definition of patient. In 1996, HRSA proposed a patient definition and then proposed a revised definition in 2015 which they then withdrew. Since the program has evolved since the original statute was written, how should these changes be reflected in how a patient is defined?
Vizient agrees the program has evolved since the original statute was written. Vizient discourages Congress from setting a definition of patient in statutory text that would align with 2015 guidance[6] as this could limit CEs’ ability to optimize the program. Vizient believes it is critical that the definition of patient not depend on or otherwise solely consider whether the medication ordered is part of a service provided by the CE and thus, determined on a prescription-by-prescription basis. Such a rigid interpretation unnecessarily limits the potential benefits of the 340B Program.

RFI Question: What factors should inform whether the CE has a meaningful relationship with a patient? Should the type of patient encounter or specific level of services provided be considered in determining whether a relationship exists between a CE and a patient? If so, how would these improve or provide additional program integrity?
Vizient understands that CEs take many different approaches to determining whether a relationship exists between a CE and patient. Care delivery and the types of services rapidly evolve, along with patient needs. As a result, we have concerns with legislative changes that would alter how patient relationship determinations are currently made, especially as specific program integrity concerns do not appear to have not been identified by HRSA since the *Genesis* decision.[7] Further, given the myriad, critical healthcare services provided to patients, such as pharmacists providing medication therapy management (MTM) services or drug infusion services, it would not be appropriate for Congress to deem certain services clinically or not clinically meaningful.

Section 5. Child Sites

The RFI notes, “[t]here have been examples in recent years of child sites that have benefitted from participation in the 340B Program but have not provided access to needed benefits in their communities” and that additional feedback is needed on how to appropriately ensure child sites are aligned with the intent of the 340B Program[8]. Vizient is concerned with this line of questioning overall because it suggests that Senators will consider policy that would potentially limit how CEs could use savings generated from child sites. Vizient notes our concern that this could be interpreted to mean that all savings from child sites need to flow back into the communities of the child, rather than utilized as the CE believes would be most appropriate.

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[6] https://www.federalregister.gov/documents/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance
[7] https://www.hrsa.gov/opa/educational-resources/patient-definition-resources
[8] In the RFI, Senators ask, “What policies should be considered to inform whether child sites located in different areas are responsible for using their 340B savings to help the underserved in the surrounding community, in the same manner as is expected of the parent entity?”

Currently, the 340B Program does not, and should not, impose requirements on CEs that would force savings generated from the program to be used in specific locations or for certain demographics, such as solely for the benefit of patients at a child site. Since the "340B Program enables CEs to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services,"[9] imposing requirements on how such savings are to be used runs directly counter to the goals of the 340B Program as fewer patients would be reached and fewer comprehensive services are likely to be provided. Vizient encourages the drafters to clarify that the intent of this section is not to dictate how CEs utilize 340B Program savings, including dictating how savings derived from a single site should be used.

RFI Question: Are there other specific policies we should consider to clarify the eligibility criteria of child sites?
Vizient appreciate the Senators' interest in identifying specific policies to clarify the eligibility criteria of child sites. Vizient is concerned that additional eligibility requirements for child sites provided in the Discussion Draft are excessively burdensome and unjustified. For example, requirements that the same financial and patient assistance policies apply at the child site and other sites operated by the CE, in addition to contract pharmacy locations as outlined in Section 8 of the Discussion Draft, imposes operational barriers and would effectively dictate how a CE's savings from the 340B Program are to be used, countering the purpose of the 340B Program.

Also, language regarding "clinically meaningful range of services"[10] may limit use of the 340B Program by potentially restricting use through MTM and infusion centers. Such language not only disregards the important role of these services for care purposes, but could also have a chilling effect, where patients may be more challenged in accessing these services as they may be less financially sustainable to offer without the benefits associated with the 340B Program.

Similarly, Vizient is concerned with requirements contemplated in the Discussion Draft and RFI that add unnecessary limitations on how child sites are utilized in the context of the 340B Program. For example, the requirement that the child site ensure that the ordering or dispensing provider of the covered outpatient drug at the child site have clinical responsibility for health care services that are directly related to the use of the covered outpatient drug purchased and dispensed under the 340B Program potentially dictates the scope of care that can be provided at the child site (e.g., this could potentially result in excluding follow-up care or referrals) or that only those drugs prescribed would eligible under the 340B Program.[11]

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[9] https://www.hrsa.gov/opa#:~:text=The%20340B%20Program%20enables%20covered,entities%20at%20significantly%20reduced%20prices.
[10] Discussion Draft, p. 14 (14-18), "The child site provides a clinically meaningful range of services, as determined by the services that 17 providers employed or contracted by 18 the child site are qualified to deliver."
[11] Vizient also notes our concern regarding a similar requirement as provided under Section 3. Contract Pharmacy.

Should changes regarding child site policy be made in legislation, Vizient suggests additional clarity be provided to ensure child sites are promptly registered for purposes of the 340B Program. Currently, there is an excessive waiting period for child site enrollment that should be streamlined[12] as this will help ensure CEs can optimize use of the 340B Program. For example, Vizient members indicated that they are not financially able to provide certain services and resources to communities until child sites enrollment in the 340B Program occurs.

RFI Question: We propose using the Medicare provider-based guidelines outlined in 42 CFR 413.65 as a framework to appropriately determine eligibility for a child site to participate in the program. Do the guidelines, as proposed, reflect how a wholly-owned child site should be clinically and financially integrated into the CE? Are there additional requirements that should be added to be sure the child site is clinically and financially integrated into the CE?
Should the Centers for Medicare and Medicaid Services (CMS) provider-based department requirements be utilized, this could help streamline registration as the Medicare Cost Report (MCR) could be used as a validation tool, versus an eligibility requirement.

RFI Question: What policies should be considered to inform whether child sites located in different areas are responsible for using their 340B savings to help the underserved in the surrounding community, in the same manner as is expected of the parent entity?
As noted above, Vizient is concerned that the drafters are considering policies that would dictate how 340B savings are to be utilized, including by shifting decisions regarding use of 340B savings to child sites. Vizient is concerned this approach would limit the ability of CEs to stretch scarce resources, while also causing more disjointed care since use of savings would be more difficult to coordinate and optimize if multiple entities independently made and implemented these decisions.

Section 6. Transparency

The Discussion Draft Explanatory Statement and Supplemental RFI indicates that the Senators believe that "requiring CEs to report detailed information regarding their program savings, policies, patient and prescription information, and then enabling that information to be publicly available by the Secretary will help ensure all stakeholders have trust and confidence that the program is being used as intended." However, the reporting requirements provided in this section would impose excessive, undue burden on CEs, create significant reporting challenges and are wholly unnecessary given the purpose of the 340B Program. For example, requiring information about the financial demographics of patients of the CE based on factors like the percentage of patients eligible for financial assistance programs and the percentage of patients who reside in a health professional shortage area (HPSA) could be challenging for the CE to report accurately as patients may decline to provide information that would be used to determine eligibility for financial assistance programs and whether a patient resides in a HPSA could be difficult to determine.

In addition, Vizient is concerned the transparency requirements do not align with the purpose of the program. For example, hospitals would be required to report information regarding "charity care" on a child site basis. Not only is this administratively challenging, it fails to account for the system-ness of many hospital and healthcare systems. Additionally, as stated, the plain language of the statute does not encourage limiting the use of scarce resources to specific sites participating in the program. Thus, it is unclear why this information would be relevant for purposes of transparency and could ultimately deter CEs from providing care based on community needs as there could be a misperception that such flexibility is not available.

Finally, we note that CEs already engage in efforts to improve transparency, as demonstrated by the wide acceptance of the American Hospital Association's 340B Principles.[13] Further, some of the required data could be redundant with information reported through the Medicare cost report or the IRS form 990, so it is unclear how multiple, similar reports would add transparency.

Section 7. Enhancing Program Integrity

The Discussion Draft would limit HRSA's ability to allow CEs to retroactively correct eligibility violations that would potentially result in new, harsh sanctions. While Vizient believes program integrity efforts and enhancements are important to preserving the 340B Program, we are concerned that excessive penalties may be imposed for minor errors that could be easily corrected.

Section 8. Preventing Duplicate Discounts

The Discussion Draft provides that the Secretary enter into a contract with an independent, third party to carry out clearinghouse duties to prevent duplicate discounts. While the various duties are noted in the Discussion Draft, such as requesting and receiving claims level data from various entities in the "most efficient and least burdensome manner practicable" and providing the manufacturer CE-submitted claims-level data so that the manufacturer may identify units of a 340B drug that may generate a rebate or discount, it is unclear how the clearinghouse would actually complete these duties and how duplicate discounts would actually be prevented. Given there is such limited information in the Discussion Draft, Vizient is unable to provide more meaningful comments regarding whether this is a reasonable approach to prevent duplicate discounts.

Should the clearinghouse concept be advanced, Vizient believes additional consideration regarding the scope of information reported is warranted, along with cybersecurity considerations. Vizient emphasizes that hospitals are reluctant to share claims level data with

[13] https://www.aha.org/initiativescampaigns/2019-10-03-hospitals-have-committed-340b-principles

manufacturers, including commercial claims. In addition, given recent activity regarding cybersecurity for other clearinghouses and that the Discussion Draft is silent on this issue, Vizient encourages Senators to consider opportunities to strengthen manufacturers' cybersecurity practices based on this recent, extremely challenging issue.[14] However, Vizient emphasizes that the 340B Program should not be used as a tool to regulate CEs cybersecurity efforts given the wide range of laws and regulations to which they must adhere.

Section 10. User Fee Program

The Discussion Draft provides a section to establish a user fee program that would assess and collect fees from CEs participating in the 340B Program, with such fees to be used for purposes for administering the user fee program and enhancing program integrity and oversight activities. Vizient opposes the creation of such a User Fee Program as it would drive savings away from CEs unnecessarily which, again, counters the intent of the program.

Conclusion

Vizient thanks the Senators for efforts to protect and enhance the 340B Program. Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank Senators for providing us the opportunity to comment on this important Discussion Draft and RFI. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

Shoshana Krilow
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[14] https://www.hhs.gov/about/news/2024/03/05/hhs-statement-regarding-the-cyberattack-on-change-healthcare.html