March 28, 2024

VIA EMAIL: Bipartisan340BRFI@mail.senate.gov

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

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

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

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

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

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

RE: SUSTAIN 340B Act Request for Information

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

As Chief Customer Officer (CCO) for The Craneware Group, previously Sentry Data Systems, I am pleased to comment on the bipartisan 340B Senate Working Group's draft of the SUSTAIN 340B Act dated February 2, 2024. We appreciate you will receive feedback from stakeholders on the entirety of the questions posed in the draft legislation; with respect for your time, we chose to respond to the specific topics where our 20 years of 340B experience informed the strongest perspectives.

The Craneware Group (AIM:CRW.L), the market leader in automated value cycle solutions, including robust 340B management and compliance applications and professional services , collaborates with U.S. healthcare providers to plan, execute, and monitor operational and financial performance so they can continue to deliver quality care to their communities. Integral to The Craneware Group's purpose is advocacy on behalf of the more 12,000 hospitals, health systems, clinics, and retail pharmacies that trust us as their partner in transforming the business of healthcare.

§2 *Sense of Congress*

First, we thank you for recognizing the foundational principles of the 340B program. These principles, which were part of the initial core tenets adopted by The Craneware Group and publicly shared with the Senate in 2018, continue to align with the fundamental objectives of 340B.

In this section, your emphasis on the historical context of the 340B program reflects a keen understanding of its genesis and purpose. Explicitly stating the intent to help entities stretch scarce federal resources is a vital step towards providing clarity to all stakeholders involved. This clear articulation of purpose will undoubtedly help align the missions of covered entities with the overarching goal of maximizing federal resources, reaching more eligible patients, and providing comprehensive safety net services.

We believe that by establishing this level of clarity, the purpose of the 340B program is set as a common ground for all parties involved. This shared understanding will not only facilitate smoother interactions but will also contribute to advancing the collective mission of improving healthcare access for those in need.

Once again, thank you for your dedication to preserving the integrity and original intent of the 340B program. We appreciate your tireless efforts in shaping policies that will positively impact the healthcare landscape**.**

§3 *Contract Pharmacy*

Patients served by Covered Entities (CEs), *especially in rural areas*, often face challenges accessing healthcare due to geographic distances. Having convenient access to prescribed medications upon returning home is crucial. However, accessing medications through approved pharmacies is often influenced more by payer contracts or manufacturers than the patient's location. This is particularly relevant for CEs providing specialty care, even if a patient travels only 30 minutes to their site.

In such cases, many patients require specialty medications for their ongoing care. Prescription fulfillment is determined either by the payer or through approval from the manufacturer for drug distribution at a designated specialty pharmacy. We offer two examples demonstrating the complexity of Contract Pharmacy arrangements beyond the control of the CE.

a. Payer contracts prevent a patient of Specialty Pharmacy A from filling their prescription at Specialty Pharmacy B, a specialty pharmacy owned by a competitor, even if Specialty Pharmacy B is geographically closer to the patient's home.
b. Certain specialty medications may only be distributed by designated specialty pharmacies based on the drug manufacturer’s selection, but often patients require multiple specialty medications. A patient may need to access one drug at Specialty Pharmacy A and another at Specialty Pharmacy B, which are both specialty pharmacies but have different distribution arrangements.

These scenarios underscore the need for CEs to establish multiple specialty contract pharmacy arrangements, considering various factors influencing access to care and medications.

Therefore, when considering the selection and geographic distribution of Contract Pharmacies, any restriction of access to 340B medications is discriminatory. Diverse populations served by different covered entity types require careful consideration, especially for specialty pharmacies. Specialty medications, often available exclusively at a limited number of pharmacies nationwide through contractual agreements with manufacturers, would face unnecessary payer-related barriers if restricted by location. The challenge of transportation for patients in outlying or underserved areas further underscores the need to factor this into decisions on limitations of contract pharmacy locations. Geographic limitations on contract pharmacies can impede patients from accessing essential medications, introducing discriminatory requirements inconsistent with the 340B program's objectives. *We firmly advocate against restrictions based on geography and pharmacy type, considering the complexities outlined above.*

Regarding Pharmacy Benefit Managers (PBMs) and their influence on the 340B program, it is imperative to prohibit pricing discrimination for prescription reimbursement based on the CE's drug acquisition cost. The 340B discount was not meant to be passed along to the PBMs and is not in alignment with the program's original intent. The 340B program's primary purpose is to support clinics and hospitals in serving their patients, prioritizing patient well-being over favoring PBMs and third-party payers.

§4 *Patient Definition*

We strongly endorse the involvement of safety-net providers as primary healthcare entities in shaping the definitions of "patient" and "meaningful service" within the 340B program. Leveraging their firsthand experience and intimate understanding of diverse patient populations, safety-net providers are uniquely positioned to contribute valuable insights. Empowering these providers to actively participate in defining these terms ensures that the 340B program aligns precisely with the unique needs and circumstances of the populations it serves, thereby enhancing its overall effectiveness and impact.

The definition of "patient" should be based upon the CE encounter, which establishes the moment a patient is initially identified for 340B eligibility, especially in instances when a patient is referred for follow-up care in the community and is issued eligible prescriptions. The program's logistical setup and various compliance mechanisms may necessitate a retrospective review and identification of eligible patients and prescriptions. The minimum date for consideration should be determined by the covered entity's enrollment in the program.

Considering the temporal aspect of the patient relationship and the legal maximum prescription fill period of one year, it is logical to set a minimum time limit of one year when establishing eligibility based on an event. This consideration is especially crucial for patients who may not promptly receive prescribed medications, such as those requiring follow-up tests or lab work before prescription issuance. If a time limit is deemed necessary, it is recommended to establish a minimum of one year, providing flexibility beyond that period to accommodate the diverse patterns of prescription issuance.

§6 *Transparency*

It is crucial to emphasize that the core purpose of 340B is to help covered entities maintain and expand safety net services to patients, extending assistance for services provided to patients, with a strong emphasis on supporting

healthcare services, rather than exclusively offering prescription discounts to individual patients. This steadfast focus ensures that the program remains aligned with its original objectives of improving healthcare accessibility and affordability for the vulnerable populations served by safety-net hospitals. We highlight several crucial points regarding the protection of 340B prices and the intricacies associated with contract pharmacy (CP) transactions:

- 340B Price Protection: The protection of 340B prices is integral to the program's effectiveness. While individual negotiations between Covered Entities (CEs) and payers occur, mechanisms are in place to safeguard 340B pricing. Transparency and accountability in these negotiations are crucial, ensuring that the intended benefits of the program are preserved.
- Deciphering Individually Negotiated Rates: We acknowledge that deciphering individually negotiated rates with payers presents challenges. The 340B program should strive to establish standardized reporting practices that maintain the confidentiality of these rates while ensuring compliance and preventing undue scrutiny.
- Dynamic Nature of 340B Data: Managing 340B data involves various factors like contract pharmacy agreements, keeping track of changes over time, deadlines for processing, and making sure there's enough inventory available. Because of these complexities, reporting requires a careful and detailed approach. Recognizing the complexities involved, focusing on reporting based upon replenishments, which is when the drugs are purchased on 340B based on prescriptions dispensed that previously qualified, offers a more accurate representation of 340B transactions. The drugs become 340B once purchased through the 340B discount program for the 340B eligible prescriptions that make up a full package for purchase.
- Manufacturer Accountability: In the interest of fairness and transparency, manufacturers must be held accountable to the same standards as a CE. Questions regarding their expenditures on charity care, including Patient Assistance Programs (PAPs), and their revenue from federal programs such as Medicaid, Medicare, VA, Tricare, etc., relative to their claimed losses in the 340B program, are valid. This balanced inquiry ensures a comprehensive understanding of the true healthcare financial landscape.

§7 *Enhancing Program Integrity*

While recognizing the Act's intent to fortify the 340B program, there are concerns about the broad scope of authority granted to HRSA, necessitating the need for clear guardrails.

Safety-net hospitals, aligning with the program's original intent, have earnestly embraced considerations of patients' economic means, demonstrating a commitment to the overarching goal of the 340B program. Notably, safety-net hospitals have conscientiously extended services based on need, without excluding individuals based on insurance status.

However, the Act's current language seems to grant HRSA extensive authority, raising concerns about potential ambiguities. To address this, we recommend that Congress provide more specific guidance, reducing ambiguity surrounding patient definitions and related aspects. By doing so, HRSA's role would transition from regulatory oversight to operationalizing the SUSTAIN Act, streamlining the implementation process and ensuring the program's integrity without requiring expansive regulatory authority.

This approach aligns with the core principles of transparency and accountability, allowing for effective program implementation while ensuring the original intent of the 340B program is maintained. Clarifying the parameters within which HRSA operates will enhance the program's success and foster confidence among stakeholders.

§8 *Preventing Duplicate Discounts*

Regarding duplicate discounts, we advocate for an approach that establishes a transparent and secure framework emphasizing data protection and impartiality:

- Clearinghouse and User Fee: We propose mimicking HRSA's successful 340B audit model, establishing that a clearinghouse should be contracted to an independent organization, such as Bizzell, to safeguard data integrity without question of conflicted interest; we detail further recommendations for *Independent Third-Party Oversight* further below in this section. Our position on *User Fees* is detailed in our review of §10.
- Conflict of Interest Safeguards: Stringent measures to prevent current and future conflicts of interest concerning the use of data must be mandated.
- Responsibility for Duplicate Discounts: We respectfully challenge the assertion that Covered Entities (CEs) should bear responsibility for duplicate discounts not caused by them. It is the contractual obligation of Pharmacy Benefit Managers (PBMs) and manufacturers to rectify duplicate discount issues, as stipulated in the contracts between them.
- Commercial Plans Inclusion and Medicaid Duplicate Discounts: We wish to clarify that the 340B statute specifically addresses Medicaid duplicate discounts. Commercial plans should not be automatically included, as responsibility for addressing such issues lies with PBMs, as outlined in their contracts with manufacturers.
- Specific Unique BIN/PCN for Medicaid Managed Care Plans: As we have for years, we advocate for issuing unique BIN/PCN combinations for Medicaid Managed Care plans, enabling CEs to report on 340B scripts to prevent state rebates on the same prescriptions, thereby eliminating the risk of duplicate discounts.
- Independent Third-Party Oversight: *The importance of an independent third party overseeing the process on behalf of the government cannot be overstated*. This safeguard guarantees impartiality and reliability in identifying duplicate discounts. *Data should remain proprietary, used only for its intended purpose, and never sold.*
- Minimum Data Points for Confirming Duplicate Discounts: A streamlined approach with a minimum number of data points to confirm duplicate discounts is essential to striking a balance between efficacy and safeguarding sensitive information.

§10 *User Fee Program*

Specifically addressing the funding mechanism for a non-conflicted clearinghouse, our recommendations focus on ensuring fairness, transparency, and reasonable administration fees.

We endorse the idea of utilizing a non-conflicted clearinghouse. The importance of transparency and impartiality to address duplicate discounts effectively is noted, and we suggest aligning with the proposed clearinghouse for Independent Review Agreements (IRA) to enhance overall program efficiency. However, we share broad concerns about the proposed administrative fee of 0.01% of benefits to be paid by the CE, deeming it excessive for these safety-net providers.

We advocate for a shared CE-manufacturer solution, including a cap on the administrative fee to prevent potential overcharging and ensure that the fee structure is proportionate to the services provided.

We respectfully request clarity on the justification for the administrative fee, urging transparency in detailing the specific services provided and the reasons behind the associated costs. We encourage a thorough examination of the differences in administering the 340B program for various entity types and highlight the need for proportionate fees.

We further recommend exploring alternative fee structures that balance the need for funding with the obligation to minimize financial burdens on covered entities and respectfully request consideration of models that allocate fees based on factors like entity size or transaction volume to promote fairness.

§11 *Studies and Reports*

Regarding the effort to establish reasonable dispensing fees associated with contract pharmacies, we offer the following perspectives, which underscore the importance of carefully considering the balance between government intervention and market dynamics.

We are cautious about extensive intervention in what is considered an open and competitive market; while it is possible for the government to provide guidance or to publish recommended dispensing fees, it must be done with no other objective than to promote transparency. We also have broad concerns regarding the complexity and granularity of determining dispensing fees, given the diverse levels and combinations of fees involved. Establishing universally applicable fees that address the unique intricacies of different healthcare settings and services will be challenging.

In that context, we have reservations about the effectiveness of recommending dispensing fees, given the intricate nature of the studies required for such an endeavor. Maintaining the integrity of these studies to ensure accurate and meaningful insights is of the utmost importance.

In conclusion, we additionally endorse and support the consideration of H.R.2534, the PROTECT 340B Act of 2023, and H.R.7635, 340B PATIENTS Act, as you continue drafting legislative provisions in the SUSTAIN 340B Act.

Once again, on behalf of The Craneware Group, I appreciate the opportunity to contribute to the RFI for the SUSTAIN 340B Act draft. The insights offered in this response by The Craneware Group reflect our decades-long operational experience and commitment to fostering a robust and equitable 340B program that aligns with Congress' core objectives for the program -- *to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.*

Thank you for considering these perspectives, and I look forward to ongoing collaboration and dialogue to enhance the integrity and effectiveness of the 340B program.
Sincerely,

Lidia A. Rodriguez-Hupp

Lidia A. Rodriguez-Hupp
Chief Customer Officer