April 1, 2024

The Honorable John Thune
Senator
S-208, The Capitol
Washington, DC 20510

The Honorable Tammy Baldwin
Senator
S-221, The Capitol
Washington, DC 20510

The Honorable Debbie Stabenow
Senator
419 Hart Senate Office Building
Washington, DC 20510

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

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

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

RE: Response to Request for Information: SUSTAIN 340B Act Discussion Draft

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

On behalf of the Louisiana Rural Health Association (LRHA), we appreciate the opportunity to provide feedback on the discussion draft of the SUSTAIN 340B Act. We appreciate the Senators' commitment to maintaining the program's integrity and original intent to stretch scarce federal resources. The 340B program plays a crucial role in allowing rural safety net providers to continue to serve their patient's needs and preserve access to care.

LRHA is a membership association that is made up of Louisiana rural health care providers. This includes rural health clinics (RHCs); rural federally qualified health centers (FQHCs); and rural hospitals across the state. LRHA works to provide a unified voice that promotes and enhances the quality of rural health in Louisiana.

LRHA appreciates the opportunity to provide input on behalf of our members towards improving access to health care for residents in rural areas.

You will find our response to your question areas below.

SECTION 2: Sense of Congress.

LRHA supports the statement of purpose for the program and stresses the importance of including this statement in the statute to avoid any ambiguity. As we have seen, all parties involved in 340B have used statutory silence on various matters to their advantage or to circumvent the original intent of Congress when the program was created. A clear statement on the purpose of the program will contribute to upholding the integrity of 340B.

Our members use the resources from this program to provide essential care in our communities. This includes a geratric-psych unit that provides 24/7 care. This unit loses money, but is able to stay afloat with the funds received from the 340B program.

SECTION 3: Contract Pharmacy

We thank the Senators for protecting contract pharmacy arrangements and including restrictions placed on manufacturers to protect such arrangements. LRHA strongly supports codifying contract pharmacy protections into the 340B statute. As manufacturers increasingly impose restrictions on contract pharmacy usage for covered entities, we are seeing untenable reductions in savings.

One of our rural providers provided an example of how their community relies heavily on four main pharmacies for their pharmaceutical needs. If patients are directed to specific pharmacies, it not only undermines fair competition but also deprives individuals of the opportunity to utilize the pharmacy that best meets their financial and personal needs. It is imperative that patients have the freedom to choose their pharmacy without being steered towards particular establishments.

We also understand the challenges faced by small local pharmacies. These establishments are not only essential pillars of our community but also sources of livelihood for many hardworking individuals. If these small pharmacies are forced to close due to financial struggles, it would have devastating consequences for our community, as patients would be left with limited options for their healthcare needs.

The Senators must clearly allow for unlimited use of contract pharmacies in the statute. Restricting the number of contract pharmacies that a covered entity may utilize would disproportionately constrain access for our patients compared to urban patients. If the Working Group includes any restrictions on the number of contract pharmacies that covered entities may contract with, we urge an exclusion for rural covered entities.

Additionally, the issue of duplicate discounts is a matter of great concern. It is disheartening to see the perception that covered entities are exploiting loopholes in the system to gain unfair advantages. Implementing measures to prevent double dipping, such as running monthly reports to identify and rectify such discrepancies, is crucial to ensuring fair competition and transparency.

We are not opposed to providing necessary information to verify the absence of duplicate discounts, as long as it is done through an independent third party to maintain the integrity and impartiality of the process.

Manufacturers are also increasingly using reporting conditions to allow covered entities to use a limited number of contract pharmacies. Covered entities often have to report claims data through the 340B ESP platform under the guise of program integrity in order to continue using contract pharmacies. We appreciate the Senators' inclusion of subsection (11)(A)(iii) to end such conditions on contract pharmacy use.

SECTION 4: Patient Definition.

It is imperative that the Senators include a definition of patient in the statute. LRHA urges the Senators to codify HRSA's 1996 patient definition in the 340B statute.[1] This definition requires that the covered entity has established a relationship with the individual such that the covered entity maintains the individual's health records and the individual receives healthcare services from a professional employed by the covered entity.[2]

In addition to HRSA's 1996 definition, there are some unique rural elements that must be addressed in a future statutory definition. First, we ask that telehealth services count as patient visits for covered entities. Especially in

[1] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 6 Fed. Reg. 55,156 (Oct. 24, 1996).
[2] *Id.*

rural areas, telehealth is an important tool for connecting patients to care and rural patients would be disproportionately left out of the 340B program if telehealth visits are not built into the patient definition as an allowable encounter.

Second, any patient definition should be inclusive of transient populations. Transient populations may include seasonal employees in rural communities with heavy seasonal recreational tourism, migrant workers on farms, or individuals in the fishing industry in remote coastal areas. When these individuals visit a covered entity for health care services, they must be considered a patient. The definition of patient should be encounter based rather than whether a covered entity is the sole provider for an individual. Oftentimes migrant workers are underserved and un- or underinsured, meaning that they are the exact population that should benefit from free or discounted drugs and other safety net services that the covered entity provides through 340B savings.

One particular issue that must be addressed is the documentation of referral patients. In order to ensure continuity of care and proper reimbursement, there must be clear evidence of the referral process and ongoing communication between healthcare providers. By requiring documentation of referrals and follow-up care, we can ensure that patients receive comprehensive and coordinated treatment plans.

Additionally, it is important to emphasize the value of closing the loop between referring providers and receiving providers. This includes ensuring that necessary documentation, such as patient notes and treatment plans, are shared between all parties involved in a patient's care. By maintaining a strong relationship between providers and proper documentation of referrals, we can ensure that patients receive the highest quality of care and that healthcare resources are utilized efficiently.

Furthermore, it is worth noting that some providers within our healthcare system have the ability to access medications at the 340B price, which is crucial for providing affordable healthcare to underserved populations. It is essential to support and expand programs that enable providers to access medications at discounted prices, thereby ensuring that patients have access to the medications they need at an affordable cost.

SECTION 5: Child Sites.

LRHA appreciates the Senators' use of Medicare provider-based guidelines as a framework for child site eligibility. Using existing regulations to determine eligibility will make determining eligibility easier for rural covered entities that likely already comply.

We have concerns about adding any additional, overly burdensome requirements to identify child sites as clinically and financially integrated. We urge the Senators to finalize this section as written to ensure there are no addiitonal requirements or unfunded mandates placed on rural covered entities and their child sites.

SECTION 6: Transparency.

LRHA appreciates the need for transparency around the 340B Program to ensure program integrity. Rural covered entities are not the entities that are misusing the program. Our members provide a great deal patient care using their scare resources and are committed to utilizing the 340B savings for their intended purpose - to retain crucial services for their patient population, like unprofitable service lines, transportation to medical appointments, and other patient support services which could not be furnished otherwise.

However, there is a concern regarding the definition of charity care as it relates the proposed required reporting. As noted above, many of our rural providers utilize 340B savings to offset losses on essential programs aimed at serving vulnerable populations in our community. These programs, while vital for promoting public health and well-being, often fall outside the traditional definition of charity care, leaving providers to bear the financial burden alone.

In addition to providing services that are reimbursable, but at a lower rate than sufficient to cover program costs, many of our rural covered entities provide non-reimbursable programs that are essential for addressing public health issues such as tobacco use, bullying, and unwanted pregnancy prevention. These programs incur significant costs for healthcare providers, including expenses related to staffing, education, and outreach efforts. However, due to their non-reimbursable nature, providers often struggle to cover these costs, hindering their ability to deliver crucial services to our community. Savings from the 340B program are often used to offset these costs to allow our rural facilities the financial capacity to provide these services.

LRHA urges the Senators to consider the potential administrative burden that extra reporting will cause for small rural covered entities. Any extra reporting is a heavy lift for providers that do not have a team dedicated to such tasks, which is likely the case for most rural covered entities. As such, the reporting elements in this section should align with data that is already being reported by covered entities for other federal programs.

SECTION 7: Enhancing Program Integrity.

LRHA supports provisions that grant HRSA more oversight and regulatory authority over the program. HRSA currently has a limited ability to regulate and requires clear statutory authority to oversee and protect the integrity of the 340B program.

We believe that rural facilities and rural pharmacies need carve-out provisions in 340B regulations, including a 3-year audit waiver, to ensure HRSA has capacity to focus on major violators. Regulations should presume rural compliance due to limited providers. Increased oversight on pharmaceutical manufacturers and punitive damages are necessary to deter future contract abuses.

SECTION 8: Preventing Duplicate Discounts.

LRHA supports creating a national clearinghouse to prevent duplicate discounts. We particularly support the provision that the Secretary must contract with an independent, third-party entity that is free of conflicts of interest with any 340B Program participants. Additionally, language to require the third-party entity to request and receive information in the least burdensome manner practicable will benefit rural covered entities that must submit claims-level data to the clearinghouse.

SECTION 9: Ensuring Equitable Treatment of Covered Entities and Pharmacies Participating in the 340B Drug Discount Program.

LRHA supports the provisions in this section to end discrimination against 340B participants. We understand that there is an administrative cost associated with dispensing medications and that should be covered for the pharmacies and pharmacy benefit managers. Unfortunately, some are charging extremely high dispensing fees which erode 340B savings for covered entities. To combat this practice, the Senators should insert language in this section to address the adequate upper limit of dispensing fees charged to covered entities. This amount should only be charged to cover the "time and materials" associated with dispensing medications or be defined as "market-based, fair, and equitable."

Relatedly, LRHA appreciates that the Working Group directs HHS to conduct a study on dispensing fees in Section 11 of this legislation. We anticipate that the information gleaned from the study will support future legislation and regulations to strengthen protections against undue dispensing fees associated with contract pharmacies.

SECTION 10: User Fee Program.

LRHA strongly believes that HRSA needs stronger oversight and administrative authority over the 340B Program, and the agency also needs increased investments and sufficient resources to do so. We thank the Senators for incorporating the User Fee Program to address this and ensure HRSA is able to carry out the requirements outlined

in this legislation. We further support Section 12, which authorizes additional appropriations for HRSA to carry out audits, investigations, and oversight and enforcement activities in the program.

Alternatively, the Working Group may consider requiring manufacturers to cover any user fees rather than place the burden on covered entities.

Other Considerations.

The Working Group did not include a major rural 340B priority in the proposed legislation, which is ending the orphan drug exclusion for rural hospitals. LRHA urges the Senators to provide critical access hospitals, sole community hospitals, and rural referral centers relief from this exclusion. The orphan drug exclusion only applies to these rural hospital designations and thus comes at an unfair cost for rural patients that require these lifesaving treatments. The availability of specialty treatments is limited in rural areas and rural hospitals typically cannot acquire these treatments without a discount. Congress must require that manufacturers provide orphan drugs at a discount for rural hospitals to ensure that patients of covered rural hospitals can access the same treatments as those at other hospitals where appropriate.

Conclusion

LRHA is thankful for the opportunity to provide input regarding needed reforms to this important program. If you would like additional information, please contact Denaé Hebert at dhebert@lrha.org or 337.366.5915.

Sincerely,

Denaé M. Hebert
Executive Director
Louisiana Rural Health Association