National Rural Health Association

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

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

The National Rural Health Association (NRHA) appreciates 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 for rural providers that allows them to continue to serve their patient's needs and preserve access to care.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

Almost 150 rural hospitals have closed their doors since 2010, with nearly 20 more having ceased inpatient services,[1] and many more have stopped critical services such as chemotherapy or obstetrics due to financial strain. When a hospital or service line closes, the impact can be devastating for a community. Hospitals are not the only rural providers that continue to struggle to stay afloat, but they are a proxy for the overall health of the rural healthcare system. Provider-based rural health clinics, community health centers, and others need support and rely upon the lifeline that is 340B to maintain services that are most important to their patients and communities.

Section 2: Sense of Congress.

NRHA supports the proposed statement of purpose for the program in the SUSTAIN 340B Act discussion draft. We stress the importance of including this statement in the statute to avoid any ambiguity regarding program intent. As we have seen, all parties involved in 340B have used

[1] Rural Hospital Closures, N.C. Rural Health Research Center, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/ (this number includes hospitals that converted to another hospital type, such as the Rural Emergency Hospital designation).

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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.

Section 3: Contract Pharmacy.

We thank the Senators for protecting contract pharmacy arrangements and including restrictions placed on manufacturers to protect such arrangements. NRHA strongly supports codifying contract pharmacy protections into the 340B statute. As manufacturers increasingly impose restrictions on contract pharmacy usage for covered entities, NRHA's members are seeing real decreases in program savings. For example, one NRHA member hospital in Missouri that participates in 340B noted that they currently provide about $300,000 per month in drug discounts to patients through their contract pharmacies. However, their ability to offer those discounts is at risk as they have lost roughly half of their contract pharmacy savings over the last three years due to restrictions. On average, these discounts were closer to $200,000 per month prior to restrictions that have grown over the past few years. Another member hospital in Michigan saw a 38% decrease in savings in 2022 compared to 2021, impacting their ability to offer critical services for patients. Last, a community health center in New Hampshire noted that a reduction in 340B savings led to closing dental health centers, a service that is severely lacking nationally in rural areas. This diminution in savings is unacceptable and untenable for many rural covered entities. Not only do reductions in savings limit covered entities' abilities to invest in new services, but it may also lead to ending certain services or closing altogether.

Further, we urge the Senators against restricting the number of contract pharmacies that a covered entity may use as this would disproportionately constrain access for rural patients compared to urban patients. Many rural covered entities are too small to support an in-house pharmacy, or their pharmacies do not have the capability to provide sufficient access to prescription drugs throughout the entire service area. Given the geographic spread of rural areas, patients of rural covered entities travel farther, thus multiple contract pharmacies are needed to ensure rural access. Following the 3rd Circuit Court of Appeals decision that manufacturers may limit contract pharmacy arrangements because the statute is silent,[2] manufacturers subsequently increased their extremely restrictive policies on covered entities.[3] Again, we applaud the Senators for working to end these practices and protect access to contract pharmacies and urge stronger and clear language against restricting the number of contract pharmacies that rural covered entities may work.

Manufacturers are also increasingly using reporting requirements for covered entities to limit the 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. NRHA appreciates the Senators' inclusion of subsection (11)(A)(iii) to end such conditions on contract pharmacy use. NRHA members are burdened by these unfair conditions imposed by manufacturers and would like clarification on whether all reporting currently being done through such portals would end when this legislative language is passed.

In subsections (B) – (D) regarding registering contracts with pharmacies and the requirements of such contracts, NRHA suggests that the Senators include more guidance on timeframes. The Secretary is charged with promulgated rulemaking, including rules for standard contract provisions that must

[2] *Sanofi Aventis U.S. LLC v. Becerra*.
[3] For example, in the weeks following the 3rd Circuit's decision, Johnson & Johnson announced that covered entities may only use one contract pharmacy. Please find other manufacturer examples here.

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be included in all contracts. To ensure that these requirements are implemented smoothly and in a reasonable manner for rural covered entities, the Senators should include language that requires the Secretary to include an adequate timeframe, for example 180 days, for covered entities to amend their contracts and comply with the future rules. The several required clauses in the legislation, once finalized through rulemaking, will be a heavy lift for rural covered entities to include in their contracts.

- **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.**
- **How would you structure any geographic restriction or other restriction on contract pharmacies to ensure patients in rural and underserved areas maintain access to drugs?**

NRHA urges the Senators against putting any restrictions on the use of contract pharmacies, geographic-based or otherwise. Rural areas are not a monolith, and each has its own unique health care delivery system and access constraints. For the reasons above that are unique to rural covered entities and their patients, all rural 340B participants should be exempt from any contract pharmacy limitations, should they be added to the statute. NRHA members have noted that their covered entity uses anywhere from two to ten contract pharmacies depending upon the needs of their community, the geographic spread of their patient population, and availability of nearby pharmacies. Rural patients are frequently older with poly-pharmacy prescription management needs that require in-person assistance by a clinical pharmacist and care team; mail order is no substitute. Rural patients and providers simply cannot face more barriers to care than they already do. Congress must clearly provide for unlimited contract pharmacy use along with no manufacturer conditions in this legislation.

We urge the Working Group to consider incorporating H.R. 7635, the *340B PATIENTS Act*, recently introduced by Representative Matsui, to protect unlimited contract pharmacy restrictions for all covered entities.[4] This legislation inserts language into the 340B statute to allow for unlimited contract pharmacy arrangements and also includes similar provisions to *SUSTAIN 340B* around prohibiting manufacturers from requiring claims data submission by covered entities. If the Senators decline to include these important protections, we urge them to exclude rural covered entities from any restrictions on the number of contract pharmacy arrangements and would be happy to provide assistance in the development of that language.

Any restrictions on contract pharmacies means that a portion of rural patients will not maintain access to 340B drugs, which is an unacceptable outcome of a reform effort. The intent of the program is, as stated by this legislation, "maintain, improve, and expand patient access to health care services" by stretching scarce federal resources. Discounted or free medications are one aspect of health care services, and a particularly important one for rural patients that are generally older, sicker, poorer, and likely managing multiple medications. It is antithetical to the stated purpose in this legislation to

[4] Text available here: https://matsui.house.gov/sites/evo-subsites/matsui.house.gov/files/evo-media-document/MATSUI_022_xml_final.pdf

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place restrictions on contract pharmacy arrangements that would hinder access to medications for patients.

Rural covered entities utilize multiple contract pharmacies because their service area is so large that one pharmacy is not accessible to all patients. Limiting choice to a certain number of contract pharmacies will not only further reduce savings for rural covered entities but even worse, it will reduce choice for patients and likely create more obstacles to getting a prescription. When patients do not adhere to their prescriptions because they cannot easily access a pharmacy, this results in worse health outcomes and ultimately more emergency department utilization because their conditions were not managed properly with their medications.

Choosing certain pharmacy arrangements over others also has a trickle-down effect that can inadvertently hurt rural independent pharmacies. Like all other rural providers, rural pharmacies are struggling to stay open.[5] By requiring a covered entity to choose one independent pharmacy over another for their contract pharmacy arrangements, the covered entity is making the difficult decision to disadvantage one independent pharmacy instead of the other. As rural communities continue to see independent pharmacies shutter, restrictions on contract pharmacy use can unintentionally worsen access for entire communities, not just 340B patients.

- **A greater number of 340B medications are now specialty medications, which can often only be obtained through specialty pharmacies. These specialty pharmacies often only have a few locations throughout the country. How would you structure any limitation on contract pharmacy while also ensuring patients have access to these specialty medications?**

In the explanatory document it is noted that specialty pharmacies have few locations nationwide. In rural areas, they are even more few and far between and yet manufacturers' restrictions on contract pharmacies often unilaterally apply to specialty pharmacies, even though these are likely the only place patients can receive specialty drugs for chronic or life-threatening diseases. For example, some manufacturers have imposed forty-mile limits from the covered entity and for rural covered entities, this may mean that they are unable to contract with a specialty pharmacy, limiting access to lifesaving treatment for rural patients.[6] We are pleased to see the Senators take decisive action to end these inequitable practices.

Section 4: Patient Definition.

Recently, the United States District Court of South Carolina used a broader definition of a "patient" in the 340B program in the *Genesis v. Becerra* case,[7] ultimately due to the fact that the statute does not define patient. However, the relief provided by the court only applied to Genesis, so its actual impact is limited and HRSA may impute its more restrictive definition of "patient" on other covered entities. For this reason, it is imperative that the Senators include a definition of patient in the statute.

[5] Markian Hawryluk, *How Rural Communities are Losing Their Pharmacies*, KFF Health News, Nov. 15, 2021, https://kffhealthnews.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/.
[6] 340B Health, Restrictions on 340B Contract Pharmacy Increase Drug Company Profits But Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety Net Hospitals, March 2023, 8, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_March_2023.pdf.
[7] *Genesis Health Care Inc. v. Becerra*.

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Fragmented court decisions on patient definition will not behoove any parties in the program nor provide needed clarity and consistency for covered entities.

NRHA urges the Senators to codify HRSA's 1996 patient definition in the 340B statute.[8] 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 who is either employed by the covered entity or provides health care under contractual or other arrangements.[9] This definition aligns with NRHA's belief that the definition of patient should be encounter based and follow the patient-provider relationship. When a patient sees a healthcare provider at a covered entity and the provider orders a prescription, they are a patient of that covered entity.

In addition to HRSA's 1996 definition, there are some unique rural elements that must be addressed in a future statutory definition. First, NRHA asks that telehealth services count as patient visits for covered entities in rural areas. Telehealth is an important tool for connecting rural patients to care and they 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.

Section 5: Child Sites.

NRHA appreciates the Senators' use of Medicare provider-based guidelines as a framework for child site eligibility. Using existing regulations will make determining eligibility easier for rural covered entities that more than likely already comply. We urge the Senators to finalize this section as written to ensure there are no additional requirements or unfunded mandates placed on rural covered entities and their child sites.

Section 6: Transparency.

NRHA appreciates the need for transparency around the 340B program. Like the Working Group, we are also committed to ensuring that the program is used for its intended purpose and benefits the communities served by covered entities. Rural covered entities use their savings according to the needs of their patient populations and communities. They are not the entities that are misusing the program. Rural providers operate on razor thin margins and rely upon 340B savings to retain crucial services for their patient population, like unprofitable service lines, transportation, and integration of behavioral and oral health care, which would not be furnished otherwise. Rural covered entities do not have the room in their budgets to misuse 340B savings or do anything other than increase access to care. As such, NRHA suggests that another reporting element may be to provide data on covered

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

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entities' bottom lines or operating margins. This data will prove useful for both HHS and anyone reviewing the information once it is publicly available online. A covered entities' financial status can illuminate their position as good stewards of 340B savings as they do not have room in their budgets to misuse any funds. Given the potential administrative burden associated with additional reporting, NRHA asks the Working Group to consider exceptions for facilities clearly not using 340B savings outside the intern of the program. For example, covered entities with historical, three-year average operating margins below a minimal baseline of 3% should be exempted from additional reporting. Alternatively, covered entities that demonstrate their cost of bad debts and charity care exceed their 340B savings should be exempted from additional reporting. The cost of bad debts and charity care can be measured using a process such as the CMS hospital cost report Worksheet S-10.

NRHA 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 additional staff 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. For example, FQHCs should use the data reported in the Uniform Data System (UDS) for 340B reporting because it addresses patient coverage and financial characteristics, services provided, clinical data and other elements related to or identical to those outlined in this section.[10] However, different providers report different data elements. For example, rural hospitals do not collect UDS data and are not capturing some of the proposed reporting elements. These facilities may be challenged to do so given the breadth of information requested and workforce constraints in most hospitals. NRHA understands that this reporting is a concession needed to ensure the integrity of the program and retain protections for covered entities elsewhere, but we are concerned about the amount of work that it will require for rural covered entities.

NRHA asks for additional guidance around the requirement to report this information one year after enactment of the legislation. Depending on when the Secretary promulgates regulations and the provider fiscal year cycles, rural covered entities may need more time to compile this information and submit it to the Secretary. Another issue raised by reporting within one year is how this timeline aligns with Medicare cost reports. The legislation proposes that the report is an addendum to the Medicare cost report. Entities submit their cost reports at various times throughout the year and complete 340B data may not be ready in time to submit as an addendum when the cost report is submitted, especially if it must be within the year after enactment. Again, depending on when covered entities submit their cost reports, the first round of data may only capture a few months of information after enactment of the legislation before it must be submitted. For both these reasons, NRHA asks that the Senators take this into account and provide clarification that: 1) The Secretary shall promulgate rules within one year of the date of enactment, 2) Covered entities shall report for their first full fiscal year that begins after promulgation of regulations.

Additionally, NRHA requests clarification around the addendum to the Medicare cost report. The Senators must include a provision for HHS to develop this addendum and make it publicly available for covered entities review and comment prior to implementation. Also, because this is a Medicare cost report, the legislation needs more specific information on whether the Centers for Medicare and Medicaid Services (CMS) will also gain access to the information and how HRSA, as the administrator of 340B, will receive the cost report addendum.

[10] You can find UDS reports FQHCs here: https://data.hrsa.gov/tools/data-reporting/program-data.

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Section 7: Enhancing Program Integrity.

NRHA 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 340B.

Section 8: Preventing Duplicate Discounts.

NRHA 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.

NRHA supports the provisions in this section to end discrimination against 340B participants. We appreciate the use of language from the PROTECT 340B Act, which NRHA has endorsed in multiple Congresses.

Section 10: User Fee Program.

NRHA strongly believes that HRSA needs stronger oversight and administrative authority over the 340B program, and we know that this means 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. The proposed 0.01% of savings that the covered entities receive from the program is small enough not to erode their overall savings, but enough across all entities to equip HRSA with adequate resources. NRHA supports the User Fee program as the funds supplement HRSA's annual appropriations from Congress to administer the program. We further support Section 12, which authorizes additional appropriations for HRSA to carry out audits, investigations, and oversight and enforcement activities in the program. We applaud the Senators for recognizing that HRSA needs the regulatory authority and the resources to go along with it.

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

Section 11: Studies and Reports.

We understand that there is an administrative cost associated with dispensing medications and that should be covered for the pharmacies. Unfortunately, some specialty pharmacies and national retail chains are charging extremely high dispensing fees which erode 340B savings for covered entities. To combat this practice, the Senators should use the results of the HHS study 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." Dispensing fees charged to rural covered entities should be higher than those charged to other larger or urban covered entities.

NRHA 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

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future legislation and regulations to strengthen protections against undue dispensing fees associated with contract pharmacies.

Other Considerations.

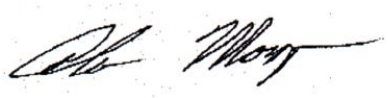
Notably absent from the proposed legislation is one of NRHA's priorities around 340B reform, which is ending the orphan drug exclusion for rural hospitals. NRHA supports providing critical access hospitals (CAHs), sole community hospitals, and rural referral centers relief from this exclusion. The orphan drug exclusion only applies to these rural hospital designations (plus freestanding cancer centers) 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.

In addition, in many cases orphan drugs are used for more common conditions and not solely for rare diseases or conditions. For example, in early 2024 a CAH in rural Indiana expanded its services to include a gastroenterology department specializing in IBD. This expansion was a positive for increasing access to specialty care in the rural area; however, the hospital is prevented from purchasing one of their main IBD therapies at the 340B discount price. About one-fifth of the hospital's IBD patients are on a particular drug that has an orphan drug indication and yet they are unable to purchase it at a 340B price.

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.

NRHA thanks the Working Group for their efforts on this important legislation and for the opportunity to submit public comments. We look forward to working with the Senators on this legislation and seeing 340B reform move forward, ensuring a benefit to all participants in the program. For any additional information, please contact NRHA's Government Affairs and Policy Director, Alexa McKinley (amckinley@ruralhealth.us).

Sincerely,



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