South Dakota
Association of Healthcare Organizations

3708 W. Brooks Place • Sioux Falls, SD 57106 • (605) 361-2281

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 South Dakota Association of Healthcare Organizations (SDAHO) 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 safety net providers that allows them to continue to serve their patient's needs and preserve access to care.

SDAHO serves as a voice for South Dakota's hospitals and healthcare organizations encompassing the full continuum of care. SDAHO members include hospitals, healthcare systems, nursing facilities, home health agencies, assisted living centers, and hospice organizations. SDAHO's mission includes advancing healthy communities across the healthcare continuum. We are a very rural state and many of our hospital members participate in the 340B program.

The 340B Program is an instrumental piece of healthcare in South Dakota. 340B entities utilize the cost savings for many programs across the state, including access to care in rural communities, statewide cancer care, rural obstetrics access, and more. Any changes to the program could potentially impact many of these services that are vital to serving the citizens of South Dakota, especially those in rural communities.

During the 2024 legislative session, our advocacy team was heavily involved in passing legislation in South Dakota to protect 340B entities from discriminatory practices by pharmacy benefit managers who have been clawing away at the 340B savings intended to go to the covered entities. HB117 is crucial legislation in our state that provides definitions for the discriminatory acts, causes for civil action, and causes for regulatory action by the South Dakota Division of Insurance. While we are helping our members in South Dakota as best we can, we genuinely appreciate your commitment to

solving these issues at the federal level to ensure our providers can continue to provide access to life saving care, especially in rural South Dakota.

Section 2: Sense of Congress.

SDAHO 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.

Section 3: Contract Pharmacy.

We thank the Senators for protecting contract pharmacy arrangements and including restrictions placed on manufacturers to protect such arrangements. SDAHO 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.

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 use 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. This not only places undue hardship on our providers in South Dakota, but that hardship gets passed along to patients. If their rural pharmacy isn't allowed to be a contract pharmacy, those patients may have to travel long distances to receive the medications they require.

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. SDAHO 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

[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.*

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.

SDAHO 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 more than likely already comply. 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.

SDAHO appreciates the need for transparency around the 340B Program. However, rural covered entities use their savings according to the needs of their patient populations and communities. They are not the participants that are misusing the program. As previously mentioned, 340B entities in South Dakota are utilizing the savings to maintain access to care in rural communities, including obstetrics and cancer care that would otherwise not be viable in those rural settings, thus causing patients to drive greater distances to receive the care they need.

Additionally, SDAHO 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. Our most rural providers in South Dakota often have staff who wear many hats and cover extra duties, especially with the workforce shortages our healthcare providers are experiencing.

Section 7: Enhancing Program Integrity.

SDAHO 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.

SDAHO 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 our members if they 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.

SDAHO supports the provisions in this section to end discrimination against 340B participants. As previously mentioned, our advocacy team recently worked to pass legislation in South Dakota during the 2024 Legislative Session that defined discriminatory acts by pharmacy benefit managers. The legislation also allowed cause for a civil suit or regulatory action by the South Dakota Division of Insurance. We also support the similar provisions in the PROTECT 340B Act, which Representative Johnson from South Dakota is a sponsor of, making sure that pharmacy benefit managers and health insurance plans aren't unfairly discriminating against health providers and contract pharmacies of the 340B program.

We understand that there is an administrative cost associated with dispensing medications and that should be covered for the pharmacies and PBMs. 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, SDAHO 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.

SDAHO 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. However, making the covered entities who are getting savings from the program cover the user fee contradicts the program's original intent. The Working Group may consider requiring manufacturers to cover any user fees rather than place the burden on covered entities. This would help to ensure that all the savings that are intended through the 340B program are going to benefit the communities being served.

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

South Dakota
Association of Healthcare Organizations

3708 W. Brooks Place • Sioux Falls, SD 57106 • (605) 361-2281

SDAHO thanks the Working Group for the opportunity to provide comments on the draft SUSTAIN 340B Act. If you would like additional information, please contact Tim Rave at Tim.Rave@sdaho.org or 605-361-2281.

Sincerely,

Tim Rave
President/CEO
South Dakota Association of Healthcare Organizations