Senate Human Services
Senator Judy Lee, Chair
March 12, 2025
HB 1473

Chair Lee and members of the Senate Human Services Committee: For the record my name is Jesse Breidenbach and I serve as vice president of pharmacy services for Sanford Health. I grew up in Reynolds, ND, I am a lifelong ND resident, and I am an NDSU college of pharmacy graduate. I have worked for Sanford in Fargo for the past 18 years, and I have worked with the 340B program at Sanford for the past 12 years dating back to when Sanford entered the 340B program.

Thank you for the opportunity to testify in support of HB 1473.

Opponents of this bill have claimed that North Dakota covered entities—hospitals and federally qualified health centers—are not meeting the intent of the 340B program and related transparency requirements. Allow me to clarify the current 340B program requirements and provide forward-looking information on this matter.

To qualify for and maintain participation in the 340B program, covered entities must comply with all reporting and audit requirements set by the Health Resources and Services Administration (HRSA), the U.S. Department of Health and Human Services agency that oversees the program. Non-compliance can result in penalties, including repayment of improperly used discounts or removal from the program. Contrary to what opponents may suggest or attempt to distract with, covered entities are committed to complying with the intent of the program and its requirements. Arguments to the contrary are an attempt to detract from the devoted rural health care and rural pharmacy services that our North Dakota providers do day in and day out.

Program Qualifications
Program qualifications are slightly different for each category of covered entities. Sanford Health hospitals in ND qualify as non-profit Disproportionate Share Hospitals (aka DSH hospitals) (Fargo and Bismarck) and critical access hospitals (Mayville and Hillsboro). Disproportionate Share Hospital is a term that refers to the percentage of patients we care for that are uninsured, covered by the Medicaid program or low income Medicare patients. The minimum DSH percentage to qualify as a 340B DSH hospital is 11.75 percent; Sanford Bismarck and Sanford Fargo's most recently filed CMS cost reports demonstrate DSH percentages of 13.65 and 14.44, respectively. In other words, Sanford Health is well established as a covered entity in the program due to our Medicaid, low income Medicare and uninsured population that we have privilege to serve.

Program Recertification
Program recertification is required on an annual basis to ensure covered entities remain compliant with the program's eligibility and operational requirements. Recertification includes the following:

- **Confirm eligibility**: Covered entities must confirm that they continue to meet the eligibility requirements including meeting the minimum DSH threshold (and various other criteria for different entity types). To prove we meet this requirement we are required to upload our CMS cost reports annually to verify our status of meeting the DSH percentage or critical access status.

- **Comply with current 340B policies and procedures**: It is the covered entity's responsibility to ensure internal policies and procedures comply and are in alignment with any new guidance or changes in the program. In HRSA audits we are required to share our 340B policy with the HRSA auditors so that HRSA has full visibility of how we conduct our program, and visibility of our policies complying with the 340B program statute and HRSA regulations and guidelines.
- **Program integrity and reporting**: Ensure accurate reporting of all required data, including history of self-audits and a summary of external consultant audits, eligible patients and any changes in operations.
    - **Attest to compliance**: Covered entities must attest that they are compliant with all 340B program requirements, including assurance that that drugs purchased under the 340B program are not resold or diverted to ineligible patients, and that we do not purchase 340B drugs for Medicaid patients if Medicaid would be seeking a rebate for the same transaction.

Covered entities must maintain supporting documentation that shows their continued compliance with the program. HRSA may audit covered entities to verify this compliance at any time, and entities need to have evidence in place to demonstrate they meet program requirements.

Covered-Entity Audit
As part of HRSA's program integrity oversight, HRSA conducts random audits of covered entities to ensure compliance with all program requirements.

The audit scope includes:
- Eligibility: Verification that the covered entity and its contract pharmacies continue to meet eligibility requirements for the 340B Program.
- Diversion: Ensuring 340B drugs are only dispensed to eligible patients (i.e., outpatients of the covered entity) and not diverted to ineligible patients.
- Duplicate discounts: Confirming that 340B drugs are not subject to both a 340B discount and a Medicaid rebate, which is prohibited under the program.
- Contract pharmacy oversight: Ensure agreements are compliant and that the covered entity monitors these pharmacies to prevent diversion or duplicate discounts.

If the audit has findings of noncompliance, covered entities typically have 60 days to provide a corrective action plan to address the issue and is subject to HRSA approval. Noncompliance may require repayment to manufacturers or removal from the 340B program. Findings are posted on a public-facing website. Most HRSA audit finding are database/registration related, not compliance related. Database findings can be as simple as an incorrect address on a registered location in HRSA's Office of Pharmacy Affairs Information System (OPAIS) database.

Manufacturer Good Faith Inquiries of 340B Program Covered Entities
HRSA expects all covered entities to respond and accommodate reasonable good faith inquires any given manufacturer might have regarding the covered entity's 340B program and purchasing of 340B drugs. Such inquiries might arise when a manufacturer has concerns about a covered entity's purchasing patterns that could suggest 340B diversion or duplicate discounts; which are both prohibited by the 340B statute. There is no formal HRSA process outlining manufacturer good faith inquiries of covered entities, but HRSA does recommend that manufacturers and covered entities work together to resolve such concerns. If a manufacturer is not satisfied

with the covered entity's engagement in the good faith inquiry, or the covered entity is not able to clarify the inquiry to the manufacturer's satisfaction a good faith inquiry could escalate to the point of a HRSA-approved manufacturer audit of the covered entity. At Sanford we have participated in several good faith inquiries over the life of our program and none of these inquires has escalated to a HRSA approved manufacturer audit of any of our covered entities.

HRSA-Approved Manufacturer Audits of 340B Program Covered Entities

To ensure accountability while balancing the interests of both manufacturers and covered entities, drug manufacturers are permitted to audit covered entities to verify compliance. This aspect cannot be overlooked – pharmaceutical manufacturers are equipped today to request an audit of covered entities. A manufacturer audit is designed to ensure that the covered entity is adhering to the rules and requirements of the 340B Program, specifically regarding the prohibition of drug diversion[1] and duplicate discounts[2].

The audit focuses on the covered entity's records directly related to the manufacturer's drugs purchased under the 340B Program. HRSA requires all entities to maintain auditable records demonstrating compliance with eligibility, patient definition and proper use of discounted drugs.

If non-compliance is found (e.g., diversion or duplicate discounts), the covered entity may be required to repay the manufacturer for discounts received improperly. Serious or repeated violations could lead to further action, such as removal from the 340B Program.

To put it plainly, covered entities are strictly scrutinized for their participation in the 340B program through oversight by HRSA, manufacturer initiated good faith inquiries or manufacturer audits, and additional enforcement levers. Conversely, pharmaceutical manufacturers are under no obligation to stay in the 340B program. This program is voluntary and if manufacturers feel the program is no longer in their best interest, they have the option to leave the program. While the same argument can be made against covered entities, we remain – and always will be – committed to ensuring access to health care in North Dakota, and this program is currently helping us meet this commitment.

Strengthening the 340B Program

When drug manufacturers say the program would benefit from targeted changes to improve transparency and strengthen the program, we agree. To that end there is good work being done at the federal level to improve upon the processes I just outlined.

A bipartisan group of six influential U.S. Senators – known as the 340B Gang of Six[3] – support and have initiated work on bipartisan legislation designed to bring more predictability, stability, transparency and accountability to the program.

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[1] Drug Diversion: Ensuring 340B drugs are not diverted to individuals who are not eligible patients of the covered entity.

[2] Duplicate Discounts: Preventing a situation where a 340B discount is applied to a drug, and the manufacturer also provides a rebate for the same drug under the Medicaid Drug Rebate Program.

[3] Sens. John Thune (R-S.D.), Debbie Stabenow (D-Mich.), Shelley Moore Capito (R-W.Va.), Tammy Baldwin (D-Wis.), Jerry Moran (R-Kan.), and Ben Cardin (D-Md.)

Recognizing such policymaking needs to be informed by the recommendations of all 340B stakeholders, the Gang of Six established a multi-sector coalition of hospitals and health systems, community health centers, and biopharmaceutical manufacturers to work together to find common ground on federal policies and make consensus-based recommendations to Congress on ways to improve the 340B program. The Gang of Six put out two separate requests for information in 2024 and received informative feedback from all stakeholders.

I have personally met with the Gang of Six on three different occasions in 2024 as part of a multidisciplinary stakeholder group. This group, known as the Working Table, included manufacturers, FQHCs, health systems and critical access hospitals. This group is truly trying to find the middle ground within the 340B program; which is what we seek to provide stability, transparency and accountability within the program at the federal level.

This work culminated in creation of draft legislation called the Sustain 340B Act. This bill was released in the form of a discussion draft in February 2024, and a legislative draft of the Act was nearly introduced in late 2024 but fell short in large part due to leadership changes that resulted from the November 2024 election. Their work, however, continues, and we expect to see a new gang of six announced in the coming weeks to pick up where the original group left off.

The bottom line is that the 340B drug discount program is a federal program and North Dakota hospitals, FQHCs and the contract pharmacies we work with are complying with all federal requirements.

Thank you for your consideration of HB 1473. I would stand for any questions you may have.

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