

2025 1473
House Industry, Business and Labor
Representative Warrey, Chairman
February 10, 2025

Chairman Warrey and members of the House Industry, Business and Labor Committee. My name is Erin Navarro, and I serve as the Director of Pharmacy at Altru Health System (Altru). I am honored to represent Altru and share my passion for ensuring patients remain at the heart of everything we do in healthcare and proud to be part of improving healthcare for the communities we serve. I write in favor of House Bill 1473 and ask that you give this bill a **Do Pass** recommendation.

Sole Community Hospital

Altru is a Sole Community Hospital (SCH) and 340B Drug Pricing Program covered entity, serving over 200,000 residents in northeast North Dakota and northwest Minnesota. As a covered entity and health system, Altru ensures that care is provided to our patients regardless of their ability to pay. To be designated as a SCH, a hospital must meet specific criteria set by the Centers for Medicare & Medicaid Services (CMS). Here are the key requirements:

1. **Location:** The hospital must be located more than 35 miles from other like hospitals. Alternatively, if the hospital is in a rural area, it can be located between 25 and 35 miles from other like hospitals, provided it meets additional criteria such as having no more than 25% of residents or Medicare beneficiaries in the hospital's service area admitted to other like hospitals within a 35-mile radius.
2. **Special Circumstances:** The hospital can also qualify if it is located between 15 and 25 miles from other like hospitals but is inaccessible for at least 30 days in each of 2 out of 3 years due to local topography or severe weather conditions.
3. **Service Area:** The hospital must draw at least 75% of its inpatients from its service area during the most recent 12-month cost reporting period.

Regarding the impact on 340B eligibility, Sole Community Hospitals must meet additional requirements to participate in the 340B Drug Pricing Program:

1. **Disproportionate Share Adjustment:** The hospital must have a disproportionate share adjustment percentage greater than or equal to 8% for the most-recently filed cost report.
2. **Non-Profit Status:** The hospital must be a private non-profit hospital under contract with state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid, or it must be owned or operated by a unit of state or local government.
3. **Certification:** The hospital must certify that it meets the statutory definition of a Sole Community Hospital and that such status is recognized by CMS.

These requirements ensure that SCH can access discounted drug prices under the 340B program, which can offer significant savings on pharmaceuticals.

Altru's 340B Program

Altru has been a covered entity in the 340B program for nearly a decade. Altru runs a conservative and compliant program, with accurate 340B policies and procedures and an internal team dedicated to those compliance standards. Annually, Altru recertifies our 340B Program to maintain compliance. The annual recertification is a vital component of maintaining the program's integrity. It ensures that only eligible entities continue to benefit from the 340B discounts, thereby preventing misuse and preserving the program's resources for those who truly need them. The recertification includes complete transparency to the federal government. This transparency includes creating a trial balance that ties every applicable line of the Medicare Cost Report to registered 340B child sites to include outpatient expense and revenue at each location 340B drugs are purchased. Altru also includes our Medicare Cost Report in full and include our government contract. Meaning our books are open and fully transparent to the federal government, namely Health Resources and Services Administration (HRSA).

In addition to this annual recertification, Altru has also responded to all HRSA requests for information and was successful in a recent HRSA audit of the Altru 340B Program which verified that Altru adheres to the program's rules and regulations, ensuring that the benefits of the 340B Program are being used appropriately to support patient care for underserved populations. The audit examines various aspects of the covered entity's participation in the 340B Program, including:

- **Eligibility:** Confirming that the entity meets the eligibility criteria for participation in the program.

- **Duplicate Discounts:** Ensuring that the entity is not receiving both a 340B discount and a Medicaid rebate for the same drug.
- **Diversion:** Checking that 340B drugs are only dispensed to eligible patients and not diverted to ineligible patients or entities.

Process: The audit process typically involves several steps:

- **Notification:** Altru was notified of the upcoming audit and provided with details 30 days in advance.
- **Documentation Review:** HRSA reviewed the Altru's uploaded records and documentation to verify compliance with 340B Program requirements.
- **Site Visit:** HRSA came to Altru to further assess compliance and gather additional information.

Outcomes: Depending on the audit findings, outcomes can range from no adverse findings to the requirement for corrective actions. In cases of significant non-compliance, entities may be required to repay manufacturers for any discounts received inappropriately or face removal from the 340B Program. Altru was thrilled to report that our organization did not have any deficiencies and successfully passed the HRSA audit in April 2022.

Community Benefit

The Altru 340B Program is crucial to the communities Altru services in that we rely on 340B savings to keep services open in our region, to include but are not limited to:

- Devils Lake Dialysis;
- Altru in and outpatient behavioral health;
- Altru's Level 2 Trauma status;
- Altru's investment in the Devils Lake Critical Access Hospital;
- Over 60 Altru specialists services;
- Altru Home Health services;
- Emergency care services to include ground and air ambulance; and
- Onsite intensivists in Altru's ICU.

Our 340B Program also support our community's low-income populations in tandem with Grand Forks BlueZones and Public Health with transportation to chemotherapy appointments and food insecurity. Altru is able to provide nurse at Grand Forks Lagrave on Frist as well as Altru's Food Pantry and other charitable care.

Unfortunately, over the past two years, Altru and Altru patients have felt the financial impact of manufacturers continuously pulling medications from the 340B Program. As of this date, Altru has received communication from 33 manufacturers pulling medications.

Impact

In the last 3 years our ability to purchase 340b drugs has been impacted by manufacturers imposing their own mandates on who they give discounts to. Most of this impact has been in the community, contract pharmacy setting. Manufacturers have limited our ability to partner with community pharmacies by prohibiting such arrangements and refusing to honor 340B discounts on certain drugs. Unfortunately, we are on the verge of needing to terminate our contracts with many independent pharmacies across the state due to big pharma's refusal to comply with the intent of the program. Let the law be followed as the legislature that drafted it intended. Don't let big pharma rewrite the laws to our state's hospitals and constituents' detriment.

I appreciate the opportunity to be part of improving healthcare across the state of North Dakota. We ask that you give the bill a Do Pass recommendation. Thank you for your consideration. I am to answer questions.

Thank you,

Erin Navarro