SENATE
STATE OF MINNESOTA
NINETY-THIRD SESSION

S.F. No. 4861

(SENATE AUTHORS: WIKLUND)

DATE	D-PG	OFFICIAL STATUS
03/11/2024	12142	Introduction and first reading Referred to Health and Human Services

A bill for an act

relating to health; modifying reporting requirements for 340B covered entities; proposing coding for new law in Minnesota Statutes, chapter 62J; repealing Minnesota Statutes 2023 Supplement, section 62J.312, subdivision 6.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62J.461] 340B COVERED ENTITY REPORT.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions apply.

(b) "340B covered entity" or "covered entity" means a covered entity as defined in United States Code, title 42, section 256b(a)(4), with a service address in Minnesota as of January 1 of the reporting year. 340B covered entity includes all entity types and grantees. All facilities that are identified as child sites or grantee associated sites under the federal 340B Drug Pricing Program are considered part of the 340B covered entity.

(c) "340B Drug Pricing Program" or "340B program" means the drug discount program established under United States Code, title 42, section 256b.

(d) "340B entity type" is the designation of the 340B covered entity according to the entity types specified in United States Code, title 42, section 256b(a)(4).

(e) "340B ID" is the unique identification number provided by the Health Resources and Services Administration to identify a 340B-eligible entity in the 340B Office of Pharmacy Affairs Information System.

(f) "Contract pharmacy" means a pharmacy with which a 340B covered entity has an arrangement to dispense drugs purchased under the 340B Drug Pricing Program.

(g) "Pricing unit" means the smallest dispensable amount of a prescription drug product that can be dispensed or administered.

Subd. 2. **Current registration.** Beginning April 1, 2024, each 340B covered entity must maintain a current registration with the commissioner in a form and manner prescribed by the commissioner. The registration must include the following information:

(1) the name of the 340B covered entity;

(2) the 340B ID of the 340B covered entity;

(3) the servicing address of the 340B covered entity; and

(4) the 340B entity type of the 340B covered entity.

Subd. 3. **Reporting by covered entities to the commissioner.** (a) Each 340B covered entity shall report to the commissioner by April 1, 2024, and by April 1 of each year thereafter, the following information for transactions conducted by the 340B covered entity or on its behalf, and related to its participation in the federal 340B program for the previous calendar year:

(1) the aggregated acquisition cost for prescription drugs obtained under the 340B program;

(2) the aggregated payment amount received for drugs obtained under the 340B program and dispensed or administered to patients;

(3) the number of pricing units dispensed or administered for prescription drugs described in clause (2); and

(4) the aggregated payments made:

(i) to contract pharmacies to dispense drugs obtained under the 340B program;

(ii) to any other entity that is not the covered entity and is not a contract pharmacy for managing any aspect of the covered entity's 340B program; and

(iii) for all other expenses related to administering the 340B program.

The information under clauses (2) and (3) must be reported by payer type, including but not limited to commercial insurance, medical assistance, MinnesotaCare, and Medicare, in the form and manner prescribed by the commissioner.

(b) For covered entities that are hospitals, the information required under paragraph (a), clauses (1) to (3), must also be reported at the national drug code level for the 50 most frequently dispensed or administered drugs by the facility under the 340B program.

(c) Data submitted to the commissioner under paragraphs (a) and (b) are classified as nonpublic data, as defined in section 13.02, subdivision 9.

Subd. 4. **Enforcement and exceptions.** (a) Any health care entity subject to reporting under this section that fails to provide data in the form and manner prescribed by the commissioner is subject to a fine paid to the commissioner of up to $500 for each day the data are past due. Any fine levied against the entity under this subdivision is subject to the contested case and judicial review provisions of sections 14.57 and 14.69.

(b) The commissioner may grant an entity an extension of or exemption from the reporting obligations under this subdivision, upon a showing of good cause by the entity.

Subd. 5. **Reports to the legislature.** By November 15, 2024, and by November 15 of each year thereafter, the commissioner shall submit to the chairs and ranking minority members of the legislative committees with jurisdiction over health care finance and policy, a report that aggregates the data submitted under subdivision 3, paragraphs (a) and (b). The data shall be aggregated in a manner that prevents the identification of an individual entity and any entity's specific data value reported for an individual data element, except that the following shall be included in the report:

(1) the information submitted under subdivision 2; and

(2) for each 340B entry identified in subdivision 2, that entity's 340B net revenue as calculated using the data submitted under subdivision 3, paragraph (a), with net revenue being subdivision 3, paragraph (a), clause (2), less the sum of subdivision 3, paragraph (a), clauses (1) and (4).

Sec. 2. **REPEALER; 340B COVERED ENTITY REPORT.**

Minnesota Statutes 2023 Supplement, section 62J.312, subdivision 6, is repealed.

62J.312 CENTER FOR HEALTH CARE AFFORDABILITY.

Subd. 6. **340B covered entity report.** (a) Beginning April 1, 2024, each 340B covered entity, as defined by section 340B(a)(4) of the Public Health Service Act, must report to the commissioner of health by April 1 of each year the following information related to its participation in the federal 340B program for the previous calendar year:

(1) the National Provider Identification (NPI) number;

(2) the name of the 340B covered entity;

(3) the servicing address of the 340B covered entity;

(4) the classification of the 340B covered entity;

(5) the aggregated acquisition cost for prescription drugs obtained under the 340B program;

(6) the aggregated payment amount received for drugs obtained under the 340B program and dispensed to patients;

(7) the aggregated payment made to pharmacies under contract to dispense drugs obtained under the 340B program; and

(8) the number of claims for prescription drugs described in clause (6).

(b) The information required under paragraph (a) must be reported by payer type, including commercial insurance, medical assistance and MinnesotaCare, and Medicare, in the form and manner defined by the commissioner. For covered entities that are hospitals, the information required under paragraph (a), clauses (5) to (8), must also be reported at the national drug code level for the 50 most frequently dispensed drugs by the facility under the 340B program.

(c) Data submitted under paragraph (a) must include prescription drugs dispensed by outpatient facilities that are identified as child facilities under the federal 340B program based on their inclusion on the hospital's Medicare cost report.

(d) Data submitted to the commissioner under paragraph (a) must be classified as nonpublic data as defined in section 13.02, subdivision 9.

(e) Beginning November 15, 2024, and by November 15 of each year thereafter, the commissioner shall prepare a report that aggregates the data submitted under paragraph (a). The commissioner shall submit this report to the chairs and ranking minority members of the legislative committees with jurisdiction over health care finance and policy.