03/25/25 REVISOR SGS/EN 25-05049 as introduced

SENATE STATE OF MINNESOTA NINETY-FOURTH SESSION

A bill for an act

relating to health; authorizing independent audits of 340B entity reporting by

OFFICIAL STATUS

S.F. No. 3271

(SENATE AUTHORS: ABELER)

1.1

1 2

DATE 04/03/2025 D-PG 1350 Introduction and first reading

Referred to Health and Human Services

nonprofit public interest organizations; requiring revenue from prescription drugs 1.3 obtained under the 340B program to be used for charity care; authorizing 1.4 enforcement by the attorney general; amending Minnesota Statutes 2024, section 1.5 62J.461, subdivision 1, by adding a subdivision; proposing coding for new law in 1.6 Minnesota Statutes, chapter 144. 1.7 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: 1.8 Section 1. Minnesota Statutes 2024, section 62J.461, subdivision 1, is amended to read: 1.9 Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions 1.10 apply. 1.11 (b) "340B covered entity" or "covered entity" means a covered entity as defined in United 1.12 States Code, title 42, section 256b(a)(4), with a service address in Minnesota as of January 1.13 1 of the reporting year. 340B covered entity includes all entity types and grantees. All 1.14 facilities that are identified as child sites or grantee associated sites under the federal 340B 1.15 Drug Pricing Program are considered part of the 340B covered entity. 1.16 (c) "340B Drug Pricing Program" or "340B program" means the drug discount program 1.17 established under United States Code, title 42, section 256b. 1.18 (d) "340B entity type" is the designation of the 340B covered entity according to the 1.19 entity types specified in United States Code, title 42, section 256b(a)(4). 1.20 (e) "340B ID" is the unique identification number provided by the Health Resources 1.21 and Services Administration to identify a 340B-eligible entity in the 340B Office of Pharmacy 1.22

Section 1.

Affairs Information System.

1.23

(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.

2.1

2.2

2.3

2.4

2.5

2.6

2.11

2.12

2.13

2.14

2.15

2.16

2.17

2.18

2.19

2.20

2.21

2.22

2.23

2.24

2.25

2.26

2.27

2.28

2.29

2.30

- (g) "Nonprofit public interest organization" means an organization operating pursuant to chapter 317A, experienced in financial or legal review, and with a purpose that includes the promotion of health care in Minnesota. Nonprofit public interest organization does not include a 340B covered entity and an affiliate of a 340B covered entity.
- 2.7 (g) (h) "Pricing unit" means the smallest dispensable amount of a prescription drug
 2.8 product that can be dispensed or administered.
- Sec. 2. Minnesota Statutes 2024, section 62J.461, is amended by adding a subdivision to read:
 - Subd. 3a. Independent audit. (a) Nonprofit public interest organizations may audit 340B covered entities to determine compliance with this section and section 144.5875.
 - (b) 340B covered entities must cooperate with a nonprofit public interest organization conducting an audit under this section and must provide all necessary data, documents, and other information, regardless of classification, that the nonprofit public interest organization requests to conduct an audit. A 340B covered entity is not required to provide any data, documents, or other information if the information is unnecessary for the completion of the audit under this section.
 - (c) Nonprofit public interest organizations must maintain all data, documents, and other information obtained pursuant to this section as confidential information and are prohibited from disclosing information to a third party. A nonprofit public interest organization may report audit results and provide recommendations to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance.

Sec. 3. [144.5875] 340B REVENUE FOR CHARITY CARE.

- Subdivision 1. Mandatory use of 340B revenue. A 340B covered entity, as defined in section 62J.461, must annually expend 25 percent of the 340B covered entity's 340B net revenue, as calculated under section 62J.461, on the provision of charity care, as defined in section 144.587. Medical debt write-offs and community service do not apply toward the required charity care expenditures required under this subdivision.
- 2.31 Subd. 2. Enforcement. In addition to the enforcement of this section by the commissioner, the attorney general may enforce this section under section 8.31.

Sec. 3. 2