

Subject 340B Reporting Requirements

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Overview

The federal 340B Drug Pricing Program allows certain health care providers (referred to as “covered entities”) to obtain discounts on covered outpatient drugs. Covered entities include several hospital types, including but not limited to disproportionate share hospitals and critical access hospitals, and also certain nonhospital providers such as federally qualified health centers. The 2023 Legislature required 340B covered entities to report specified information related to their participation in the 340B program to the commissioner of health on an annual basis, beginning April 1, 2024, and required the commissioner to annually report aggregated information to the legislature beginning November 15, 2024. This bill modifies these reporting requirements and also recodifies the 340B reporting provisions.

Summary

Section	Description
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1	340B covered entity report.
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Adds § 62J.461.

Subd. 1. Definitions. Defines the following terms: 340B covered entity, 340B Drug Pricing Program, 340B entity type, 340B ID, contract pharmacy, and pricing unit. (These terms are not defined in the current 340B reporting provision.)

Subd. 2. Current registration. Beginning April 1, 2024, requires each 340B covered entity to maintain a current registration with the commissioner. Requires the registration to include: (1) the name of the covered entity; (2) the 340B ID of the entity; (3) the serving address of the entity; and (4) the 340B entity type. (Current law requires the covered entity to report information but does not require registration; the reporting of the information in clauses (1) and (3) is required under current law, clause (2) is a new requirement, and clause (4) modifies current language.)

Section	Description
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Subd. 3. Reporting by covered entities to the commissioner. (a) Requires each 340B covered entity to report to the commissioner, by April 1, 2024, and by each April 1 thereafter, the following payment and cost information related to participation in the 340B program: (1) the aggregated acquisition cost for 340B drugs obtained (required under current law); (2) the aggregated payment amount received for 340B drugs dispensed or administered to patient (reporting for drugs dispensed is required under current law); (3) the number of pricing units dispensed or administered under clause (2) (a new provision); and (4) the aggregated payments made to: (i) contract pharmacies; (ii) other entities for program management; and (iii) for all other administrative expenses (items (ii) and (iii) are not referenced in current law). Also incorporates current law requirements related to reporting the information in clauses (2) and (3) by payer type.

(b) Incorporates the current law requirement that hospitals report specified information for the 50 most frequently dispensed or administered drugs (current law requires this reporting only for drugs that are dispensed).

(c) Incorporates the current law provision classifying the data submitted as nonpublic data.

Subd. 4. Enforcement and exceptions. Adds language on enforcement that is not included in current law. Paragraph (a) provides that any entity that fails to provide data in the form and manner specified by the commissioner is subject to a fine, to be paid to the commissioner, of up to \$500 for each day the data are past due. States that any fine levied is subject to contested case and judicial review provisions. Paragraph (b) allows the commissioner to grant an extension or exemption for an entity, upon a showing of good cause.

Subd. 5. Reports to the legislature. Incorporates the current law requirement that the commissioner report aggregate data submitted by covered entities annually to the legislature, beginning November 15, 2024, and each November 15 thereafter. Adds a new provision that requires data to be aggregated in a manner that prevents identification of an individual entity or any entity's specific data value for an individual data element, except that the following must be included in the report: (1) the information submitted in subdivision 2 as part of the registration; and (2) the 340B net revenue for each entity, calculated as specified.

2	Repealer; 340B covered entity report.
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Repeals section 62J.312, subdivision 6 (the 340B covered entity reporting provision in current law).



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