Bill Summary

# H.F. 1246

As amended by H1246DE3

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| Subject | Prescription Drug Price Transparency |
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## Overview

This bill requires drug manufacturers to report specified information on drug prices and costs to the commissioner of health, for prescription drugs whose price increases exceed certain limits, and for new prescription drugs and newly acquired prescription drugs whose price exceeds certain dollar thresholds. The bill also directs the commissioner to post certain information on drug prices and report annually to the legislature on issues related to drug pricing and spending.

## Summary

| Section | Description |
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| 1 | **Prescription drug price transparency.** Adds § 62J.84. |

**Subd. 1. Short title.** States that this section may be cited as the "Prescription Drug Price Transparency Act."

**Subd. 2. Definitions.** Defines the following terms: biosimilar, brand name drug, commissioner, generic drug, manufacturer, new prescription drug, patient assistance program, prescription drug, and price. "Commissioner" is defined as the commissioner of health and "price" is defined as the wholesale acquisition cost.

**Subd. 3. Prescription drug price increases reporting.** (a) Beginning October 1, 2021, requires drug manufacturers to submit to the commissioner of health the information described in paragraph (b), for each prescription drug priced at $100 or more for a 30-day supply or course of treatment lasting less than 30 days, for:

(1) brand name drugs whose price increases by 10 percent or more in a 12-month period or 16 percent or more in a 24-month period; and

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(2) generic drugs whose price increases by 50 percent or more in a 12-month period.

(b) For those drugs described in paragraph (a), requires a manufacturer to submit to the commissioner within 60 days of the price increase, in the form and manner prescribed by the commissioner, the following information:

(1) name and price of the drug and the net increase;

(2) the factors that contributed to the price increase;

(3) name of any available generic version;

(4) the introductory price when approved for marketing and the net yearly increase during the previous five years;

(5) the direct costs incurred by the manufacturer related to manufacture, marketing, and distribution;

(6) the total sales revenue for the drug during the previous 12-month period;

(7) the manufacturer's net profit attributable to the drug during the previous 12-month period;

(8) the total amount of financial assistance provided through any patient assistance programs;

(9) any agreement contingent upon any delay in marketing a generic version;

(10) the patent expiration date;

(11) name and location of the company; and

(12) if a brand name drug, the ten highest prices paid for the drug during the previous calendar year in any country other than the U.S.

(c) Allows the manufacturer to submit any documentation necessary to support the information reported.

**Subd. 4. New prescription drug price reporting.** (a) Beginning October 1, 2021, requires a manufacturer to report to the commissioner the following information within 60 days of introducing a new brand name drug with a price greater than the tier threshold established by the Centers for Medicare and Medicaid Services (CMS) for a 30-day supply of specialty drugs for the Medicare Part D program or a new generic or biosimilar drug with a price greater than the tier threshold established by CMS for a 30-day supply of specialty drugs for the Medicare Part D

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program that is not at least 15 percent lower than the referenced brand name drug when the generic or biosimilar drug is launched:

(1) the price of the drug;

(2) whether the FDA granted the drug a breakthrough therapy designation or priority review;

(3) direct costs incurred by the manufacturer related to manufacture, marketing, and distribution; and

(4) the patent expiration date.

(b) Allows the manufacturer to submit documentation necessary to support the information reported.

**Subd. 5. Newly acquired prescription drug reporting.** (a) Beginning October 1, 2021, requires drug manufacturers to submit to the commissioner the information described in paragraph (b), for each newly acquired prescription drug priced $100 or more for a 30-day supply or course of treatment lasting less than 30 days, for:

(1) newly acquired brand name drugs whose price increases by 10 percent or more in a 12-month period or 16 percent or more in a 24-month period; and

(2) newly acquired generic drugs whose price increases by 50 percent or more in a 12-month period.

(b) For those drugs described in paragraph (a), requires the acquiring manufacturer to submit to the commissioner within 60 days after beginning to sell the drug, in the form and manner prescribed by the commissioner, the following information:

(1) the price of the drug at acquisition and in the prior calendar year;

(2) name of the company from which the drug was acquired and related information;

(3) year the drug was introduced and the price of the drug at the time of introduction;

(4) the price of the drug for the previous five years;

(5) any agreement contingent upon any delay in marketing a generic version; and

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(6) the patent expiration date.

(c) Allows the manufacturer to submit any documentation necessary to support the information reported.

**Subd. 6. Public posting of prescription drug price information.** (a) Requires the commissioner to post on the department web site a list of drugs reported under subdivisions 3, 4, and 5 and the manufacturers, and the information reported under those subdivisions. Allows the commissioner to contract with a private entity or consortium that satisfies the standards in section 62U.04, subdivision 6, to meet this requirement.

(b) Requires the information to be published in an easy to read format and in a manner that identifies the information on a per-drug basis. Prohibits aggregation that prevents the identification of a drug.

(c) Prohibits the commissioner or the entity under contract from posting information that is not public data or is trade secret information, and specifies related procedures.

(d) Requires the commissioner to post a report on information withheld and the basis for withholding the information.

**Subd. 7. Consultation.** (a) Allows the commissioner to consult with a private entity or consortium that satisfies the requirements of section 62U.04, subdivision 6, the University of Minnesota, or the commissioner of commerce, on the form and format of information posted and other implementation issues.

(b) Allows the commissioner to consult with representatives of manufacturers to establish a standard reporting format and to use existing reporting methodologies.

**Subd. 8. Enforcement and penalties.** (a) Provides that a manufacturer may be subject to a civil penalty for failing to submit timely reports, failing to provide information, or providing inaccurate or incomplete information.

(b) Directs the commissioner to adopt a schedule of civil penalties, not to exceed $10,000 per day, based on the severity of each violation.

(c) Requires the commissioner to impose civil penalties as provided in section 144.99, subdivision 4 (general health department procedures for administrative penalties).

(d) Allows the commission to remit or mitigate civil penalties.

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(e) Requires penalties collected to be deposited in the health care access fund.

**Subd. 9. Legislative report.** By January 15, 2022, and annually each January 15 thereafter, requires the commissioner to report to the legislature on implementation, including the effectiveness of addressing goals related to promoting transparency in pricing, enhancing understanding of spending trends, and assisting in management of pharmaceutical costs. Requires the report to include a summary of the information submitted by manufacturers under subdivisions 3, 4, and 5.