MN HOUSE RESEARCH

Bill Summary

H.F. 1246

First Engrossment

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
1	**Prescription drug price transparency act.** Adds § 151.80. States that sections 151.80 to 151.83 shall be known as the Prescription Drug Price Transparency Act.
2	**Definitions.** Adds § 151.81. Defines the following terms: commissioner, new prescription drug, patient assistance program, prescription drug, price, and profit.
3	**Reporting prescription drug prices.** Adds § 62J.83.

Subd. 1. Applicability. Requires manufacturers to report the information described in subdivisions 2, 3, and 4 to the commissioner of health, beginning October 1, 2019.

Subd. 2. Prescription drug price increases reporting. For prescription drugs priced more than $40 for a course of therapy, whose price increases by 10 percent or more in a 12-month period or 16 percent or more in a 24-month period, requires a manufacturer to report to the commissioner at least 60 days in advance of the increase, the following information on drug pricing and drug costs:

(1) the wholesale acquisition cost (WAC) of the drug for each of the previous five calendar years;

(2) the price increase as a percentage of the drug's price for each of the last five calendar years;

(3) the price at initial launch;

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

(5) the introductory price when approved for marketing;

(6) directs costs incurred by the manufacturer related to manufacture, marketing, research and development, distribution, other administrative costs, and profit;

(7) percentage of the price spent on developing, manufacturing, and distributing the drug;

(8) a description of any change or improvement in the drug that necessitates the price increase;

(9) the amount of financial assistance provided through any patient assistance program;

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

(11) the patent expiration date;

(12) research and development costs paid using public funds;

(13) any other information the manufacturer deems relevant; and

(14) supporting documentation.

Subd. 3. New prescription drug price reporting. For new brand name prescription drugs priced over $500 for a 30-day supply or generics priced over $200 for a 30-day supply, requires a manufacturer to report to the commissioner within 60 days of introduction, the following information on drug pricing and drug costs:

(1) the wholesale acquisition cost of the drug;

(2) the price at initial launch;

(3) the factors that contributed to the price;

(4) direct costs incurred by the manufacturer related to manufacture, marketing, research and development, distribution, other administrative costs, and profit;

(5) percentage of the price spent on developing, manufacturing, and distributing the drug;

(6) the amount of financial assistance provided through any patient assistance program;

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

(8) the patent expiration date;

(9) research and development costs paid using public funds;

(10) any other information deemed relevant by the manufacturer; and

(11) supporting documentation.

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Subd. 4. Newly acquired prescription drug reporting. For newly acquired brand name prescription drugs priced over $100 for a 30-day supply or generics priced over $50 for a 30-day supply, requires the manufacturer to report to the commissioner at least 60 days in advance of acquisition, the following information on drug pricing and drug costs:

(1) the wholesale acquisition cost 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 WAC of the drug at the time of introduction;

(4) the WAC for the previous five years;

(5) direct costs incurred by the manufacturer related to manufacture, marketing, research and development, distribution, other administrative costs, and profit;

(6) percentage of the price projected to be spent on developing, manufacturing, and distributing the drug;

(7) the amount of financial assistance provided through any patient assistance program;

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

(9) the patent expiration date;

(10) research and development costs paid using public funds; and

(11) if available, the price as determined reasonable through effectiveness measures.

Subd. 5. Comparison data. Allows the commissioner to use any publicly available price information to verify prices reported by manufacturers.

Subd. 6. Additional information requested. Allows the commissioner to make a written request to a manufacturer for supporting documentation or additional information.

Subd. 7. Public posting of prescription drug price information. (a) Requires the commissioner to post on the department web site, 30 days before a price change is effective, a list of drugs reported by a manufacturer and the information reported under subdivisions 2 to 6.

(b) Prohibits the commissioner from posting information that is not public data or information not related to the price of a drug that the commissioner determines is not in the public interest to disclose.

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	(c) Requires the commissioner to announce the posting and allow for public comment. (d) Requires the commissioner to post a report on information withheld. **Subd. 8. Consultation.** Allows the commissioner to consult with a nonprofit dedicated to collecting and reporting health data, and the commissioner of commerce, on the form and format of information posted and other implementation issues. **Subd. 9. Legislative report.** By January 15, 2021, and annually each January 15 thereafter, requires the commissioner to report to the legislature on implementation, including the effectiveness of addressing specified goals. Specifies other criteria for the report.
4	**Enforcement and penalties.** Adds § 151.84. **Subd. 1. Civil monetary penalties.** Provides that a manufacturer may be subject to a civil penalty for failing to submit timely reports, failing to provide information, failing to respond in a timely manner to requests for additional information, and providing inaccurate or incomplete information. **Subd. 2. Enforcement.** Directs the commissioner to adopt a schedule of penalties, based on severity. Directs the commissioner to impose civil penalties as provided in law governing agency administrative penalties. Allows the commissioner to remit or mitigate civil penalties. Requires civil penalties to be paid to the commissioner of management and budget and deposited in the health care access fund.