SENATE
STATE OF MINNESOTA
NINETY-FIRST SESSION

S.F. No. 1640

(SENATE AUTHORS: ROSEN, Little, Hayden, Draheim and Nelson)

DATE	D-PG	OFFICIAL STATUS
02/25/2019		Introduction and first reading
		Referred to Health and Human Services Finance and Policy

A bill for an act

relating to health; establishing the Prescription Drug Price Transparency Act; requiring a report; proposing coding for new law in Minnesota Statutes, chapter 151.

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

Section 1. **[151.80] PRESCRIPTION DRUG PRICE TRANSPARENCY ACT.**

Sections 151.80 to 151.83 shall be known as the "Prescription Drug Price Transparency Act."

Sec. 2. **[151.81] DEFINITIONS.**

Subdivision 1. **Applicability.** Only for purposes of sections 151.80 to 151.83, the terms defined in this section have the meanings given.

Subd. 2. **Commissioner.** "Commissioner" means the commissioner of health.

Subd. 3. **New prescription drug.** "New prescription drug" means a prescription drug approved for marketing by the United States Food and Drug Administration (FDA) for which no previous wholesale acquisition cost has been established for comparison.

Subd. 4. **Patient assistance program or program.** "Patient assistance program" or "program" means a program that a manufacturer offers to the general public in which a consumer may reduce the out-of-pocket costs for prescription drugs paid by the consumer by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or other reduction in out-of-pocket costs by other means.

Subd. 5. **Prescription drug.** "Prescription drug" has the meaning provided in section 151.44, paragraph (d).

Subd. 6. **Price.** "Price" means the wholesale acquisition cost as defined in United States Code, title 42, section 1395w-3a(c)(6)(B).

Subd. 7. **Profit.** "Profit" means the total sales revenue for a prescription drug during the previous calendar year and the manufacturer's profit attributable to the same prescription drug during the previous calendar year.

Sec. 3. **[151.83] REPORTING PRESCRIPTION DRUG PRICES.**

Subdivision 1. **Applicability.** No later than October 1, 2019, a manufacturer shall report the information described in subdivisions 2, 3, and 4 to the commissioner according to the requirements in subdivision 2, 3, or 4 as applicable.

Subd. 2. **Prescription drug price increases reporting.** For every prescription drug priced more than $40 for a course of therapy, whose price increases by more than ten percent in a 12-month period or more than 16 percent in a 24-month period, the manufacturer shall report to the commissioner at least 60 days in advance of the increase, in the form and manner prescribed by the commissioner, the following information in a form and format the commissioner has determined is appropriate for public display:

(1) the wholesale acquisition cost of the drug for each of the last five calendar years, as applicable;

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

(3) the price of the drug at its initial launch;

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

(5) the introductory price of the prescription drug when it was approved for marketing by the FDA;

(6) the direct costs incurred by the manufacturer that are associated with the drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs;

(iii) to research and develop the prescription drug;

(iv) to distribute the prescription drug;

(v) other administrative costs; and

(vi) profit;

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

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

(9) the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

(10) any agreement between a manufacturer and another party contingent upon any delay in offering to market a generic version of the manufacturer's drug;

(11) the patent expiration date of the drug if it is under patent;

(12) the research and development costs associated with the prescription drug that were paid using public funds;

(13) any other information that the manufacturer deems relevant to the price increase described in this subdivision; and

(14) the documentation necessary to support the information reported under this subdivision.

Subd. 3. **New prescription drug price reporting.** For every new prescription drug that is a brand name drug that is priced over $500 for a 30-day supply or a generic name drug that is priced over $200 for a 30-day supply, 60 days or less after a manufacturer introduces a new prescription drug for sale in the United States, the manufacturer shall notify the commissioner, in the form and manner prescribed by the commissioner, of all the following information in a form and format the commissioner has determined is appropriate for public display:

(1) the wholesale acquisition cost of the drug;

(2) the price of the drug at its initial launch;

(3) the factors that contributed to the price;

(4) the direct costs incurred by the manufacturer that are associated with that drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs;

(iii) to research and develop the prescription drug;

(iv) to distribute the prescription drug;

(v) other administrative costs; and

(vi) profit;

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

(6) the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

(7) any agreement between a manufacturer and another party contingent upon any delay in offering to market a generic version of the manufacturer's drug;

(8) the patent expiration date of the drug if it is under patent;

(9) the research and development costs associated with the prescription drug that were paid using public funds;

(10) any other information that the manufacturer deems relevant to the price described in this subdivision; and

(11) the documentation necessary to support the information reported under this subdivision.

Subd. 4. **Newly acquired prescription drug price reporting.** For every newly acquired prescription drug that is a brand name drug that is priced over $100 for a 30-day supply or a generic name drug that is priced over $50 for a 30-day supply, the acquiring manufacturer shall report to the commissioner at least 60 days in advance of the acquisition, in the form and manner prescribed by the commissioner, the following information in a form and format the commissioner has determined is appropriate for public display:

(1) the wholesale acquisition cost at the time of acquisition and in the calendar year prior to acquisition;

(2) the name of the company from which the drug was acquired, the date acquired, and the purchase price;

(3) the year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction;

(4) the previous five calendar years' wholesale acquisition cost of the newly acquired brand name drug or newly acquired generic name drug;

(5) the direct costs incurred by the manufacturer that are associated with the drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs;

(iii) to research and develop the prescription drug;

(iv) to distribute the prescription drug;

(v) other administrative costs; and

(vi) profit;

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

(7) the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program;

(8) any agreement between a manufacturer and another party contingent upon any delay in offering to market a generic version of the manufacturer's drug;

(9) the patent expiration date of the drug if it is under patent;

(10) the research and development costs associated with the prescription drug that were paid using public funds; and

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

Subd. 5. **Comparison data.** The commissioner may use any publicly available prescription drug price information the commissioner deems appropriate to verify that manufacturers have properly reported price increases as required by subdivision 2 of this section.

Subd. 6. **Additional information requested.** After receiving the report or information described in subdivision 2, 3, 4, or 5, the commissioner may make a written request to the manufacturer for supporting documentation or additional information concerning the report.

Subd. 7. **Public posting of prescription drug price information.** (a) Except as provided in paragraph (c), the commissioner shall post to the department's website 30 days before a price change is effective the information from the manufacturer, in an easy-to-read format, that includes all of the following information:

(1) a list of the prescription drugs reported under subdivisions 2, 3, and 4 and the manufacturers of those prescription drugs; and

(2) information reported to the commissioner under subdivisions 2 to 6.

The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow for identification of the drug.

(b) The commissioner may not post to the department's website any information described in this section if:

(1) the information is not public data under section 13.02, subdivision 8a; and

(2) the commissioner determines that public interest does not require disclosure of the information that is unrelated to the price of a prescription drug.

(c) The commissioner shall publicly announce the posting of information required under paragraph (a) and shall allow the public to comment on the posted information for a minimum of 30 calendar days.

(d) If the commissioner withholds any information from public disclosure pursuant to this subdivision, the commissioner shall post to the department's website a report describing the nature of the information and the commissioner's basis for withholding the information from disclosure.

Subd. 8. **Consultation.** The commissioner may consult with a nonprofit dedicated to collecting and reporting health care data and the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section in posting information on the department's website pursuant to subdivision 7, and in taking any other action for the purpose of implementing this section.

Subd. 9. **Legislative report.** (a) No later than January 15, 2021, and annually on January 15 every year thereafter, the commissioner shall report to the chairs and ranking members of the committees with jurisdiction over commerce, health and human services, and state finance and operations on the implementation of the Prescription Drug Price Transparency Act, including but not limited to the effectiveness in addressing the following goals:

(1) promoting transparency in pharmaceutical pricing for the state and other payers;

(2) enhancing understanding about pharmaceutical spending trends; and

(3) assisting the state and other payers in management of pharmaceutical costs.

(b) The report shall include a summary of the information reported to the commissioner under subdivisions 2 to 7 as well as a summary of any public comments received.

(c) The report shall include recommendations for legislative changes, if any, to reduce the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the State Employee Group Insurance Program, the Department of Human Services, and health insurance premiums in the fully insured markets.

Sec. 4. **[151.84] ENFORCEMENT AND PENALTIES.**

Subdivision 1. **Civil monetary penalties.** A manufacturer may be subject to a civil penalty, as provided in subdivision 2, for:

(1) failing to submit timely reports or notices as required by section 151.83;

(2) failing to provide information required under section 151.83;

(3) failing to respond in a timely manner to a written request by the commissioner for additional information under section 151.83, subdivision 6; or

(4) providing inaccurate or incomplete information under section 151.83.

Subd. 2. **Enforcement.** (a) A manufacturer that fails to report or provide information as required by section 151.83 may be subject to a civil penalty as provided in this section.

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

(c) The commissioner shall impose civil penalties under this section as provided in section 144.99, subdivision 4.

(d) The commissioner may remit or mitigate civil penalties under this section upon terms and conditions the commissioner considers proper and consistent with public health and safety.

(e) Civil penalties collected under this section shall be paid to the commissioner of management and budget and deposited in the health care access fund to be made available for people served by state public health care programs.