State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-SECOND SESSION

H. F. No. 4504

03/23/2022 Authored by Morrison
The bill was read for the first time and referred to the Committee on Health Finance and Policy

A bill for an act

relating to health; modifying provisions for prescription drug price transparency; amending Minnesota Statutes 2020, section 62J.84, as amended.

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

Section 1. Minnesota Statutes 2020, section 62J.84, as amended by Laws 2021, chapter 30, article 3, sections 5 to 9, is amended to read:

62J.84 PRESCRIPTION DRUG PRICE TRANSPARENCY.

Subdivision 1. **Short title.** This section may be cited as the "Prescription Drug Price Transparency Act."

Subd. 2. **Definitions.** (a) For purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under United States Code, title 42, section 262(K)(3).

(c) "Brand name drug" means a drug that is produced or distributed pursuant to:

(1) an original, new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or

(2) a biologics license application approved under United States Code, title ~~45~~ 42, section 262(a)(c).

(d) "Commissioner" means the commissioner of health.

(e) "Course of treatment" means the total dosage of a single prescription for a prescription drug recommended by the Food and Drug Administration (FDA)-approved prescribing label. If the FDA-approved prescribing label includes more than one recommended dosage for a single course of treatment, the course of treatment is the maximum recommended dosage on the FDA-approved prescribing label.

~~(e)~~ (f) "Generic drug" means a drug that is marketed or distributed pursuant to:

(1) an abbreviated new drug application approved under United States Code, title 21, section 355(j);

(2) an authorized generic as defined under Code of Federal Regulations, title ~~45~~ 42, section 447.502; or

(3) a drug that entered the market the year before 1962 and was not originally marketed under a new drug application.

~~(f)~~ (g) "Manufacturer" means a drug manufacturer licensed under section 151.252.

(h) "National Drug Code" means the three-segment code maintained by the FDA that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one "0" has been added to the front of each segment containing less than the specified number of digits so that each segment contains the specified number of digits.

~~(g)~~ (i) "New prescription drug" or "new drug" means a prescription drug approved for marketing by the United States Food and Drug Administration for which no previous wholesale acquisition cost has been established for comparison.

~~(h)~~ (j) "Patient assistance program" means a program that a manufacturer offers to the public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or by other means.

~~(i)~~ (k) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision 8.

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

(m) "30-day supply" means the total daily dosage units of a prescription drug recommended by the prescribing label approved by the FDA for 30 days. If the FDA-approved prescribing label includes more than one recommended daily dosage, the 30-day supply is based on the maximum recommended daily dosage on the FDA-approved prescribing label.

Subd. 3. **Prescription drug price increases reporting.** (a) Beginning January 1, 2022, a drug manufacturer must submit to the commissioner the information described in paragraph (b) for each prescription drug for which the price was $100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days and:

(1) for brand name drugs where there is an increase of ten percent or greater in the price over the previous 12-month period or an increase of 16 percent or greater in the price over the previous 24-month period; and

(2) for generic or biosimilar drugs where there is an increase of 50 percent or greater in the price over the previous 12-month period.

(b) For each of the drugs described in paragraph (a), the manufacturer shall submit to the commissioner no later than 60 days after the price increase goes into effect, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the name, description, and price of the drug and the net increase, expressed as a percentage~~;~~, with the following listed separately:

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size;

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

(3) the name of any generic version of the prescription drug available on the market;

(4) the introductory price of the prescription drug when it was introduced for sale in the United States and the price of the drug on the last day of each of the five calendar years preceding the price increase when it was approved for marketing by the Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(5) the direct costs incurred during the previous 12-month period by the manufacturer that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

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

(iii) to distribute the prescription drug;

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

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

(8) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs during the previous 12-month period, if applicable;

(9) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the prescription drug;

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

(11) the name and location of the company that manufactured the drug; ~~and~~

(12) if a brand name prescription drug, the ten highest prices paid for the prescription drug during the previous calendar year in ~~any country other than~~ the ten countries, excluding the United States~~.~~, that charged the highest single price for the prescription drug; and

(13) if the prescription drug was acquired by the manufacturer during the previous 12-month period, all of the following information:

(i) price at acquisition;

(ii) price in the calendar year prior to acquisition;

(iii) name of the company from which the drug was acquired;

(iv) date of acquisition; and

(v) acquisition price.

(c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.

Subd. 4. **New prescription drug price reporting.** (a) Beginning January 1, 2022, no later than 60 days after a manufacturer introduces a new prescription drug for sale in the United States that is a new brand name drug with a price that is greater than the tier threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the

Medicare Part D program for a 30-day supply or for a course of treatment lasting less than 30 days or a new generic or biosimilar drug with a price that is greater than the tier threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program for a 30-day supply or for a course of treatment lasting less than 30 days and is not at least 15 percent lower than the referenced brand name drug when the generic or biosimilar drug is launched, the manufacturer must submit to the commissioner, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the description of the drug, with the following listed separately:

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size

~~(1)~~ (2) the price of the prescription drug;

~~(2)~~ (3) whether the Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

~~(3)~~ (4) the direct costs incurred by the manufacturer that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

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

(iii) to distribute the prescription drug; and

~~(4)~~ (5) the patent expiration date of the drug if it is under patent.

(b) The manufacturer may submit documentation necessary to support the information reported under this subdivision.

Subd. 5. **Newly acquired prescription drug price reporting.** (a) Beginning January 1, 2022, the acquiring drug manufacturer must submit to the commissioner the information described in paragraph (b) for each newly acquired prescription drug for which the price was $100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days and:

(1) for a newly acquired brand name drug where there is an increase of ten percent or greater in the price over the previous 12-month period or an increase of 16 percent or greater in price over the previous 24-month period; and

(2) for a newly acquired generic drug where there is an increase of 50 percent or greater in the price over the previous 12-month period.

(b) For each of the drugs described in paragraph (a), the acquiring manufacturer shall submit to the commissioner no later than 60 days after the acquiring manufacturer begins to sell the newly acquired drug, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the description of the drug, with the following listed separately:

(i) National Drug Code;

(ii) product name;

(iii) dosage form;

(iv) strength; and

(v) package size

~~(1)~~ (2) the price of the prescription drug at the time of acquisition and in the calendar year prior to acquisition;

~~(2)~~ (3) the name of the company from which the prescription drug was acquired, the date acquired, and the purchase price;

~~(3)~~ (4) the year the prescription drug was introduced to market and the price of the prescription drug at the time of introduction;

~~(4)~~ (5) the price of the prescription drug for the previous five years;

~~(5)~~ (6) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the manufacturer's drug; and

~~(6)~~ (7) the patent expiration date of the drug if it is under patent.

(c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.

Subd. 6. **Public posting of prescription drug price information.** (a) The commissioner shall post on the department's website, or may contract with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, to meet this requirement, the following information:

(1) a list of the prescription drugs reported under subdivisions 3, 4, and 5, and the manufacturers of those prescription drugs; and

(2) information reported to the commissioner under subdivisions 3, 4, and 5.

(b) The information must be published in an easy-to-read format and in a manner that identifies the information that is disclosed on a per-drug basis and must not be aggregated in a manner that prevents the identification of the prescription drug.

(c) The commissioner shall not post to the department's website or a private entity contracting with the commissioner shall not post any information described in this section if the information is not public data under section 13.02, subdivision 8a; or is trade secret information under section 13.37, subdivision 1, paragraph (b); or is trade secret information pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended. If a manufacturer believes information should be withheld from public disclosure pursuant to this paragraph, the manufacturer must clearly and specifically identify that information and describe the legal basis in writing when the manufacturer submits the information under this section. If the commissioner disagrees with the manufacturer's request to withhold information from public disclosure, the commissioner shall provide the manufacturer written notice that the information will be publicly posted 30 days after the date of the notice.

(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.

(e) To the extent the information required to be posted under this subdivision is collected and made available to the public by another state, by the University of Minnesota, or through an online drug pricing reference and analytical tool, the commissioner may reference the availability of this drug price data from another source including, within existing appropriations, creating the ability of the public to access the data from the source for purposes of meeting the reporting requirements of this subdivision.

Subd. 7. **Consultation.** (a) The commissioner may consult with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, the University of Minnesota, or the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section; in posting information pursuant to subdivision 6; and in taking any other action for the purpose of implementing this section.

(b) The commissioner may consult with representatives of the manufacturers to establish a standard format for reporting information under this section and may use existing reporting methodologies to establish a standard format to minimize administrative burdens to the state and manufacturers.

Subd. 8. **Enforcement and penalties.** (a) A manufacturer may be subject to a civil penalty, as provided in paragraph (b), for:

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

(2) failing to provide information required under this section; or

(3) providing inaccurate or incomplete information under this section.

(b) The commissioner shall adopt a schedule of civil 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 deposited in the health care access fund.

Subd. 9. **Legislative report.** (a) No later than May 15, 2022, and by January 15 of each year thereafter, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section, 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 the understanding on pharmaceutical spending trends; and

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

(b) The report must include a summary of the information submitted to the commissioner under subdivisions 3, 4, and 5.