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) a 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 42, section 262(a)(c).

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

(e) "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 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) "Manufacturer" means a drug manufacturer licensed under section 151.252.

(g) "New prescription drug" or "new 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.

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

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

(k) "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.

(l) "Course of treatment" means the total dosage of a single prescription for a prescription drug recommended by the 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.

(m) "Drug product family" means a group of one or more prescription drugs that share a unique generic drug description or nontrade name and dosage form.

(n) "National drug code" means the three-segment code maintained by the federal Food and Drug Administration 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 such that each segment contains the specified number of digits.

(o) "Pharmacy" or "pharmacy provider" means a community/outpatient pharmacy as defined in Minnesota Rules, part 6800.0100, subpart 2, that is also licensed as a pharmacy by the Board of Pharmacy under section 151.19.

(p) "Pharmacy benefit manager" or "PBM" means an entity licensed to act as a pharmacy benefit manager under section 62W.03.

(q) "Pricing unit" means the smallest dispensable amount of a prescription drug product that could be dispensed or administered.

(r) "Rebate" means a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point of sale, as part of retrospective financial reconciliations, including reconciliations that also reflect other contractual arrangements, or by any other method. Rebate does not mean a bona fide service fee as defined in Code of Federal Regulations, title 42, section 447.502.

(s) "Reporting entity" means any manufacturer, pharmacy, pharmacy benefit manager, wholesale drug distributor, or any other entity required to submit data under this section.

(t) "Wholesale drug distributor" or "wholesaler" means an entity that is licensed to act as a wholesale drug distributor under section 151.47.

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 description and price of the drug and the net increase, expressed as a percentage, with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the 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 year the prescription drug was introduced for sale in the United States;

(5) 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;

(6) 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;

(7) the number of units of the prescription drug sold during the previous 12-month period;

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

(9) the total rebate payable amount accrued for the prescription drug during the previous 12-month period;

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

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

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

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

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

(15) if a brand name prescription drug, the highest price paid for the prescription drug during the previous calendar year in the ten countries, excluding the United States, that charged the highest single price for the prescription drug; and

(16) 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 fewer 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 fewer 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) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the price of the prescription drug;

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

(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

(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. MS 2022 [Repealed, 2023 c 70 art 2 s 43]

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 11 to 14 and the manufacturers of those prescription drugs;

(2) a list of reporting entities that reported prescription drug price information under subdivisions 3, 4, and 11 to 14; and

(3) information reported to the commissioner under subdivisions 3, 4, and 11 to 14, aggregated on a per-drug basis in a manner that does not allow the identification of a reporting entity that is not the manufacturer of the drug.

(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 reporting entity believes information should be withheld from public disclosure pursuant to this paragraph, the reporting entity must clearly and specifically identify that information and describe the legal basis in writing when the reporting entity submits the information under this section. If the commissioner disagrees with the reporting entity's request to withhold information from public disclosure, the commissioner shall provide the reporting entity 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 reporting entities 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 reporting entities.

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

(1) failing to register under subdivision 15;

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

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

(4) 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 11 to 14.

Subd. 10. **Notice of prescription drugs of substantial public interest.** (a) No later than January 31, 2024, and quarterly thereafter, the commissioner shall produce and post on the department's website a list of prescription drugs that the commissioner determines to represent a substantial public interest and for which the commissioner intends to request data under subdivisions 11 to 14, subject to paragraph (c). The commissioner shall base its inclusion of prescription drugs on any information the commissioner determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state, and the commissioner shall consider drug product families that include prescription drugs:

(1) that triggered reporting under subdivision 3 or 4 during the previous calendar quarter;

(2) for which average claims paid amounts exceeded 125 percent of the price as of the claim incurred date during the most recent calendar quarter for which claims paid amounts are available; or

(3) that are identified by members of the public during a public comment process.

(b) Not sooner than 30 days after publicly posting the list of prescription drugs under paragraph (a), the department shall notify, via email, reporting entities registered with the department of:

(1) the requirement to report under subdivisions 11 to 14; and

(2) the reporting period for which data must be provided.

(c) The commissioner must not designate more than 500 prescription drugs as having a substantial public interest in any one notice.

(d) Notwithstanding subdivision 16, the commissioner is exempt from chapter 14, including section 14.386, in implementing this subdivision.

Subd. 11. **Manufacturer prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a manufacturer must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the manufacturer by the department under subdivision 10;

(2) which the manufacturer manufactures or repackages;

(3) for which the manufacturer sets the wholesale acquisition cost; and

(4) for which the manufacturer has not submitted data under subdivision 3 during the 120-day period prior to the date of the notification to report.

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

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

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the price of the drug product on the later of:

(i) the day one year prior to the date of the notification to report;

(ii) the introduced to market date; or

(iii) the acquisition date;

(3) the price of the drug product on the date of the notification to report;

(4) the year the prescription drug was introduced for sale in the United States;

(5) 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 date of the notification to report;

(6) the direct costs incurred during the reporting period specified in the notification to report by the manufacturers 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;

(7) the number of units of the prescription drug sold during the reporting period specified in the notification to report;

(8) the total sales revenue for the prescription drug during the reporting period specified in the notification to report;

(9) the total rebate payable amount accrued for the prescription drug during the reporting period specified in the notification to report;

(10) the manufacturer's net profit attributable to the prescription drug during the reporting period specified in the notification to report;

(11) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs during the reporting period specified in the notification to report, if applicable;

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

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

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

(15) if the prescription drug is a brand name prescription drug, the ten countries other than the United States that paid the highest prices for the prescription drug during the previous calendar year and their prices; and

(16) if the prescription drug was acquired by the manufacturer within the reporting period specified in the notification to report, all of the following information:

(i) the price at acquisition;

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

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

(iv) the date of acquisition; and

(v) the acquisition price.

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

Subd. 12. **Pharmacy prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a pharmacy must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the pharmacy by the department under subdivision 10; and

(2) that the pharmacy dispensed in Minnesota or mailed to a Minnesota address.

(b) For each of the drugs described in paragraph (a), the pharmacy shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

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

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of units of the drug acquired during the reporting period specified in the notification to report;

(3) the total spent before rebates by the pharmacy to acquire the drug during the reporting period specified in the notification to report;

(4) the total rebate receivable amount accrued by the pharmacy for the drug during the reporting period specified in the notification to report;

(5) the number of pricing units of the drug dispensed by the pharmacy during the reporting period specified in the notification to report;

(6) the total payment receivable by the pharmacy for dispensing the drug including ingredient cost, dispensing fee, and administrative fees during the reporting period specified in the notification to report;

(7) the total rebate payable amount accrued by the pharmacy for the drug during the reporting period specified in the notification to report; and

(8) the average cash price paid by consumers per pricing unit for prescriptions dispensed where no claim was submitted to a health care service plan or health insurer during the reporting period specified in the notification to report.

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

(d) The commissioner may grant extensions, exemptions, or both to compliance with the requirements of paragraphs (a) and (b) by small or independent pharmacies, if compliance with paragraphs (a) and (b) would represent a hardship or undue burden to the pharmacy. The commissioner may establish procedures for small or independent pharmacies to request extensions or exemptions under this paragraph.

Subd. 13. **PBM prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a PBM must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the PBM by the department under subdivision 10; and

(2) for which the PBM fulfilled pharmacy benefit management duties for Minnesota residents.

(b) For each of the drugs described in paragraph (a), the PBM shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

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

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of pricing units of the drug product filled during the reporting period specified in the notification to report;

(3) the total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled during the reporting period specified in the notification to report;

(4) the total reimbursement amount accrued and receivable from payers for pricing units of the drug product filled during the reporting period specified in the notification to report;

(5) the total administrative fee amount accrued and receivable from payers for pricing units of the drug product filled during the reporting period specified in the notification to report;

(6) the total rebate receivable amount accrued by the PBM for the drug product during the reporting period specified in the notification to report; and

(7) the total rebate payable amount accrued by the PBM for the drug product during the reporting period specified in the notification to report.

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

Subd. 14. **Wholesale drug distributor prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a wholesale drug distributor that distributes prescription drugs, for which it is not the manufacturer, to persons or entities, or both, other than a consumer or patient in the state, must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the wholesale drug distributor by the department under subdivision 10; and

(2) that the wholesale drug distributor distributed within or into Minnesota.

(b) For each of the drugs described in paragraph (a), the wholesale drug distributor shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

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

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of units of the drug product acquired by the wholesale drug distributor during the reporting period specified in the notification to report;

(3) the total spent before rebates by the wholesale drug distributor to acquire the drug product during the reporting period specified in the notification to report;

(4) the total rebate receivable amount accrued by the wholesale drug distributor for the drug product during the reporting period specified in the notification to report;

(5) the number of units of the drug product sold by the wholesale drug distributor during the reporting period specified in the notification to report;

(6) gross revenue from sales in the United States generated by the wholesale drug distributor for the drug product during the reporting period specified in the notification to report; and

(7) total rebate payable amount accrued by the wholesale drug distributor for the drug product during the reporting period specified in the notification to report.

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

Subd. 15. **Registration requirements.** A reporting entity subject to this chapter shall register, or update existing registration information, with the department in a form and manner prescribed by the commissioner by January 30 each year.

Subd. 16. **Rulemaking.** For the purposes of this section, the commissioner may use the expedited rulemaking process under section 14.389.

History: *2020 c 78 s 1; 2021 c 30 art 3 s 5-9; 2023 c 70 art 2 s 8-21; 2024 c 127 art 59 s 4; 1Sp2025 c 3 art 2 s 6-14*