HOUSE BILL NO. 710

INTRODUCED BY K. SULLIVAN

A BILL FOR AN ACT ENTITLED: "AN ACT ESTABLISHING THE PRESCRIPTION DRUG PRICE TRANSPARENCY ACT; REQUIRING REPORTING OF PRESCRIPTION DRUG COST INFORMATION; PROVIDING FOR A REPORTING FEE; ESTABLISHING PENALTIES; PROVIDING DEFINITIONS; AND PROVIDING RULEMAKING AUTHORITY."

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

NEW SECTION. **Section 1. Short title.** [Sections 1 through 7] may be cited as the "Prescription Drug Price Transparency Act".

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 7], the following definitions apply:

(1) "Department" means the department of justice provided for in 2-15-2001.

(2) "Drug" means a substance:

(a) recognized as a drug in any official compendium or supplement;

(b) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a human or other animal;

(c) other than food, intended to affect the structure or function of the body of humans or other animals; and

(d) intended for use as a component of a substance specified in subsections (2)(a), (2)(b), or (2)(c).

(3) "Health care facility" means:

(a) a freestanding birthing center; or

(b) any of the following as the terms are defined in 50-5-101:

(i) a hospital or critical access hospital;

(ii) a long-term care facility;

(iii) an outpatient center for surgical services; or

(iv) an outpatient end-stage renal dialysis facility.

(4) "Health care provider" means a person licensed or certified under Title 37 or Title 50 to provide health care services in the ordinary course of business or practice of a profession.

(5) (a) "Manufacture" means the production, preparation, propagation, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis.

(b) The term includes the repacking and relabeling of a product or package for further sale or for distribution without a further transaction.

(6) "Manufacturer" means:

(a) a person approved by application to the United States food and drug administration to manufacture a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262;

(b) a person who manufactures a product as defined in section 360eee of the Drug Supply Chain Security Act, 21 U.S.C. 301, et seq., or a biologic pursuant to 42 U.S.C. 262 that is not the subject of an approved application or license by the United States food and drug administration;

(c) a colicensed partner of a person described in subsection (6)(a) or (6)(b) that obtains the product directly from a person described in subsection (6)(a), (6)(b), or (6)(d); or

(d) an affiliate of a person described in subsection (6)(a), (6)(b), or (6)(c) that receives the product directly from a person described in subsection (6)(a), (6)(b), or (6)(c).

(7) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for a prescription drug by using coupons or discount cards, receiving copayment assistance, or by other means.

(8) "Prescription drug" means:

(a) any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 353(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.;

(b) a biological product as defined in 42 U.S.C. 262; or

(c) a bioequivalent as defined in 37-7-502.

(9) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

NEW SECTION. **Section 3. Manufacturer prescription drug price reporting -- information required -- reporting fee.** (1) On or before July 1 of each year, a manufacturer shall report annually to the department

on prescription drug prices as required in this section.

(2) The information required under this section must be reported for each prescription drug for which:

(a) the price increased by more than 10% during the reporting period established in subsection (4) over the previous calendar year; and

(b) the price was $100 or more for:

(i) a one-month supply; or

(ii) a course of treatment lasting less than one month.

(3) For each prescription drug described in subsection (2), a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) the name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the previous calendar year;

(b) the length of time the prescription drug has been on the market;

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

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

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

(f) the research and development costs associated with the prescription drug that were paid by the manufacturer;

(g) the direct costs incurred by the manufacturer to:

(i) manufacture the prescription drug;

(ii) market the prescription drug;

(iii) distribute the prescription drug; and

(iv) conduct ongoing safety and effectiveness research associated with the prescription drug;

(h) direct-to-consumer advertising costs;

(i) health care provider detailing costs;

(j) the total amount spent on lobbying expenses at the state and national levels;

(k) the costs associated with:

(i) obtaining a patent for the prescription drug and for any associated drug delivery device; and

(ii) patent litigation involving the drug;

(l) the total sales revenue for the prescription drug during the previous calendar year;

(m) the manufacturer's profit attributable to the prescription drug during the previous calendar year;

(n) the introductory price of the prescription drug when it was approved for marketing by the U.S. food and drug administration and the net yearly increase, by calendar year, in the drug's price during the previous 5 years;

(o) the 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(p) any other information that the manufacturer considers relevant to the price increase described in subsection (2); and

(q) the documentation necessary to support the information reported under this subsection (3).

(4) The report must:

(a) provide the required information for the calendar year prior to the year in which the report must be filed; and

(b) for the percentage calculation required under subsection (2)(a), compare the prices in that calendar year to the previous calendar year.

(5) The department may use any prescription drug price information the department considers appropriate to verify that manufacturers have properly reported price increases as required under this section.

(6) A manufacturer shall provide with its report the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs included in the report:

(a) the number of consumers who participated in the program;

(b) the total value of the coupons, discounts, copayment assistance, or other reductions in costs provided to consumers in this state who participated in the program;

(c) for each drug, the number of refills that qualify for the program, if applicable;

(d) if the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) the eligibility criteria for the program and how eligibility is verified for accuracy.

(7) (a) Beginning March 15, 2020, a manufacturer that introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the centers for medicare and medicaid services for specialty drugs in the medicare Part D program shall provide the department, in the form and manner prescribed by the department, with:

(i) a description of the marketing used in the introduction of the new prescription drug;

(ii) the methodology used to establish the price of the new prescription drug;

(iii) whether the U.S. food and drug administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(iv) if the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(v) the manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(vi) the research and development costs associated with the new prescription drug that were paid using public funds.

(b) The manufacturer shall provide the information 30 days or less after introducing the new prescription drug for sale in the United States.

(8) (a) After receiving the information required under this section, the department may make a written request to the manufacturer for supporting documentation or additional information. The department shall prescribe by rule:

(i) the period following the receipt of the information during which the department may request additional information; and

(ii) the period following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period provided under subsection (8)(a)(ii) as necessary, on a case-by-case basis.

(9) The report required under this section must be accompanied by the fee established by the department by rule.

NEW SECTION. **Section 4. Insurer reporting on prescription drug prices.** On or before April 1 each year, an insurer regulated under Title 33, chapters 22, 30, 31, or 35, that issues a disability policy, certificate of insurance, or membership contract that includes a prescription drug benefit shall report the following information to the department regarding prescription drugs reimbursed by the issuer in the previous calendar year:

(1) the 25 most frequently prescribed drugs under the issuer's medical benefit plans and pharmacy benefit plans;

(2) the 25 drugs that caused the greatest increase in total plan spending over the prior calendar year for the issuer's medical benefit plans and pharmacy benefit plans; and

(3) the impact of the cost of prescription drugs on each premium dollar.

NEW SECTION. **Section 5. Prescription drug price transparency -- report to legislature -- exceptions -- consumer reporting option.** (1) The department shall compile and report the information collected by the department under [sections 3 and 4] to:

(a) the children, families, health, and human services interim committee no later than September 15 of each year; and

(b) the legislative clearinghouse as provided in 5-11-210.

(2) The report must include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on:

(a) consumers;

(b) state-administered programs that pay for prescription drugs, including the state employee group benefit plan;

(c) other public employee benefit plans; and

(d) health insurance premiums in the commercial market.

(3) (a) The report may not include any information:

(i) that contains a trade secret as defined in 30-14-402; and

(ii) for which the public interest does not require disclosure of the information.

(b) If the department withholds information from public disclosure pursuant to this subsection (3), the department shall describe the nature of the information and the department's basis for withholding the information from disclosure.

(4) A person may request information that is withheld under subsection (3). The request must be made in accordance with Title 2, chapter 6, part 10. The person may appeal a denial of the request to district court as provided in 2-6-1009.

(5) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

NEW SECTION. **Section 6. Penalties.** (1) A manufacturer may be subject to a civil penalty for:

(a) failing to timely submit reports or notices;

(b) failing to provide information required under [sections 1 through 7];

(c) failing to respond in a timely manner to a written request by the department for additional information under [sections 1 through 7]; or

(d) providing inaccurate or incomplete information under [sections 1 through 7].

(2) The department shall adopt a schedule of penalties, not to exceed $10,000 per day per violation. The penalty must be based on the severity of the violation.

(3) (a) The department shall collect the penalties provided for in this section and use the money to offset the costs of administering [sections 1 through 7]. Excess money from the penalties must be deposited in the general fund.

(b) Penalties are due and payable 10 days after they are assessed.

(c) The department may adjust the reporting fee required under [section 3] if money from penalties reduces the department's costs of administering [sections 1 through 7].

(4) The department may remit or mitigate a penalty upon terms and conditions the department considers proper and consistent with the public health and safety.

NEW SECTION. **Section 7. Rulemaking.** The department may adopt rules as necessary for carrying out the provisions of [sections 1 through 7], including but not limited to rules establishing:

(1) the form and manner for reporting the information required under [sections 1 through 7];

(2) penalties for violations of [section 1 through 7]; and

(3) the reporting fee to be paid by manufacturers for the costs of carrying out the provisions of [sections 1 through 7].

NEW SECTION. **Section 8. Codification instruction.** [Sections 1 through 7] are intended to be codified as an integral part of Title 30, chapter 14, and the provisions of Title 30, chapter 14, apply to [sections 1 through 7].

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