SENATE
STATE OF MINNESOTA
NINETY-FIRST SESSION

S.F. No. 1098

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DATE	D-PG	OFFICIAL STATUS
02/11/2019	332	Introduction and first reading Referred to Health and Human Services Finance and Policy
03/27/2019	1380a	Comm report: To pass as amended and re-refer to Judiciary and Public Safety Finance and Policy

A bill for an act

relating to health; establishing the Prescription Drug Price Transparency Act; requiring rebates to be remitted to health plan companies to reduce premiums; requiring health plan companies to report on the cost of the most expensive prescription drugs and their relation to premium rates; authorizing pharmacists to dispense certain prescription drugs in emergency situations; requiring the Board of Pharmacy to provide information on its website regarding possible resources for consumers to access lower cost prescription drugs; requiring a report; amending Minnesota Statutes 2018, sections 62K.07; 151.01, subdivision 23; 151.06, by adding a subdivision; 151.211, subdivision 2, by adding a subdivision; proposing coding for new law in Minnesota Statutes, chapters 62J; 62Q; 214.

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

Section 1. **[62J.84] PRESCRIPTION DRUG PRICE TRANSPARENCY.**

Subdivision 1. **Short title.** Sections 62J.84 and 62J.85 may be cited as the "Prescription Drug Price Transparency Act."

Subd. 2. **Definitions.** (a) For purposes of this section and section 62J.85, the terms defined in this subdivision have the meanings given.

(b) "Aggregate amount of rebate" means all pharmacy rebates received by a health plan company for individual and small group health plans used to reduce health insurance premiums for individual and small group health plans.

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

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

(e) "New prescription 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.

(f) "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.

(g) "Prescription drug" or "drug" has the meaning provided in section 151.44, paragraph (d).

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

Subd. 3. **Prescription drug price increases reporting.** (a) Beginning July 1, 2020, a drug manufacturer must submit to the commissioner the information described in paragraph (b) for each prescription drug for which:

(1) the price was $100 or greater for a one-month supply or for a course of treatment lasting less than one month; and

(2) there was a net increase of ten 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:

(1) the name and price of the drug and the net increase, expressed as a percentage;

(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 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 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;

(iii) to research and develop the prescription drug; and

(iv) 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, 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; and

(11) the ten highest prices paid for the prescription drug during the previous calendar year in any country other than the United States.

(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 March 15, 2020, 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 $500 for a 30-day supply or a new generic drug with a price that is greater than $200 for a 30-day supply, the manufacturer must submit to the commissioner, in the form and manner prescribed by the commissioner, the following information:

(1) the price of the prescription drug;

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

(3) 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 research and develop the prescription drug, if the prescription drug was developed by the manufacturer;

(iv) other administrative costs; and

(4) 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 July 1, 2020, for every newly acquired prescription drug for which the price increases by more than $100 from the price before the acquisition and the price after the acquisition, the acquiring manufacturer must submit to the commissioner at least 60 days after the acquiring manufacturer begins to sell the newly acquired prescription drug, in the form and manner prescribed by the commissioner, the following information:

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

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

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

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

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

(b) 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) Except as provided in paragraph (c), 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 any information described in this section if:

(1) 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

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

(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. 7. **Consultation.** (a) The commissioner may consult with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, and 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 manufacturers to establish a standard format for reporting information under this section 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 January 15 of each year, beginning January 15, 2021, 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.

Subd. 10. **Nonseverability.** If any particular section, subdivision, or provision of this section or section 62J.85, or the application thereof to any person or circumstance, is enjoined in full or in part by a court or is held invalid, the remainder of this section and section 62J.85 and the application of any subdivision or provision of this section and section 62J.85 to other persons or circumstances shall also be invalid and not in effect.

Sec. 2. **[62J.85] USE OF COMPENSATION TO LOWER PREMIUMS.**

(a) All compensation remitted by or on behalf of a drug manufacturer that is received by a pharmacy benefit manager for actual or estimated drug utilization by enrollees of the pharmacy benefit manager's health plan company client must be remitted to and retained by the health plan company and used by the health plan company to reduce premiums.

(b) By March 1 of each year, beginning March 1, 2022, each health plan company shall file with the commissioner in a manner and form prescribed by the commissioner:

(1) the aggregate amount of rebates that the health plan company received directly from drug manufacturers or was remitted to the health plan company from pharmacy benefit managers; and

(2) how the health plan company has complied with paragraph (a) for the previous plan year.

(c) For purposes of this section, "compensation" means direct or indirect financial benefit, including rebates, discounts, credits, fees, or grants.

Sec. 3. Minnesota Statutes 2018, section 62K.07, is amended to read:

62K.07 INFORMATION DISCLOSURES.

Subdivision 1. **In general.** (a) A health carrier offering individual or small group health plans must submit the following information in a format determined by the commissioner of commerce:

(1) claims payment policies and practices;

(2) periodic financial disclosures;

(3) data on enrollment;

(4) data on disenrollment;

(5) data on the number of claims that are denied;

(6) data on rating practices;

(7) information on cost-sharing and payments with respect to out-of-network coverage; and

(8) other information required by the secretary of the United States Department of Health and Human Services under the Affordable Care Act.

(b) A health carrier offering an individual or small group health plan must comply with all information disclosure requirements of all applicable state and federal law, including the Affordable Care Act.

(c) Except for qualified health plans sold on MNsure, information reported under paragraph (a), clauses (3) and (4), is nonpublic data as defined under section 13.02, subdivision 9. Information reported under paragraph (a), clauses (1) through (8), must be reported by MNsure for qualified health plans sold through MNsure.

Subd. 2. **Prescription drug costs.** (a) Each health carrier that offers a prescription drug benefit in its individual health plans or small group health plans shall include in the applicable rate filing required under section 62A.02 the following information about covered prescription drugs:

(1) the 25 most frequently prescribed drugs in the previous plan year;

(2) the 25 most costly prescription drugs as a portion of the individual health plan's or small group health plan's total annual expenditures in the previous plan year;

(3) the 25 prescription drugs that have caused the greatest increase in total individual health plan or small group health plan spending in the previous plan year; and

(4) the projected impact of the cost of prescription drugs on premium rates.

(b) The commissioner of commerce, in consultation with the commissioner of health, shall release a summary of the information reported in paragraph (a) at the same time as the information required under section 62A.02, subdivision 2, paragraph (c).

Subd. 3. **Enforcement.** ~~(d)~~ The commissioner of commerce shall enforce this section.

EFFECTIVE DATE. This section is effective for individual health plans and small group health plans offered, issued, sold, or renewed on or after January 1, 2021.

Sec. 4. **[62Q.528] DRUG COVERAGE IN EMERGENCY SITUATIONS.**

A health plan that provides prescription drug coverage must provide coverage for a prescription drug dispensed by a pharmacist under section 151.211, subdivision 3, under the terms of coverage that would apply had the prescription drug been dispensed according to a prescription.

Sec. 5. Minnesota Statutes 2018, section 151.01, subdivision 23, is amended to read:

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, or licensed advanced practice registered nurse. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A. For purposes of sections 151.15, subdivision 4; 151.211, subdivision 3; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A.

Sec. 6. Minnesota Statutes 2018, section 151.06, is amended by adding a subdivision to read:

Subd. 6. **Information provision; sources of lower cost prescription drugs.** (a) The board shall publish a page on its website that provides regularly updated information concerning:

(1) patient assistance programs offered by drug manufacturers, including information on how to access the programs;

(2) the prescription drug assistance program established by the Minnesota Board of Aging under section 256.975, subdivision 9;

(3) the websites through which individuals can access information concerning eligibility for and enrollment in Medicare, medical assistance, MinnesotaCare, and other government-funded programs that help pay for the cost of health care;

(4) availability of providers that are authorized to participate under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b;

(5) having a discussion with the pharmacist or the consumer's health care provider about alternatives to a prescribed drug, including a lower cost or generic drug if the drug prescribed is too costly for the consumer; and

(6) any other resource that the board deems useful to individuals who are attempting to purchase prescription drugs at lower costs.

(b) The board must prepare educational materials, including brochures and posters, based on the information it provides on its website under paragraph (a). The materials must be in a form that can be downloaded from the board's website and used for patient education by pharmacists and by health care practitioners who are licensed to prescribe. The board is not required to provide printed copies of these materials.

(c) The board shall require pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established under paragraph (a).

Sec. 7. Minnesota Statutes 2018, section 151.211, subdivision 2, is amended to read:

Subd. 2. **Refill requirements.** Except as provided in subdivision 3, a prescription drug order may be refilled only with the written, electronic, or verbal consent of the prescriber and in accordance with the requirements of this chapter, the rules of the board, and where applicable, section 152.11. The date of such refill must be recorded and initialed upon the original prescription drug order, or within the electronically maintained record of the original prescription drug order, by the pharmacist, pharmacist intern, or practitioner who refills the prescription.

Sec. 8. Minnesota Statutes 2018, section 151.211, is amended by adding a subdivision to read:

Subd. 3. **Emergency prescription refills.** (a) A pharmacist may, using sound professional judgment and in accordance with accepted standards of practice, dispense a legend drug

without a current prescription drug order from a licensed practitioner if all of the following conditions are met:

(1) the patient has been compliant with taking the medication and has consistently had the drug filled or refilled as demonstrated by records maintained by the pharmacy;

(2) the pharmacy from which the legend drug is dispensed has record of a prescription drug order for the drug in the name of the patient who is requesting it, but the prescription drug order does not provide for a refill, or the time during which the refills were valid has elapsed;

(3) the pharmacist has tried but is unable to contact the practitioner who issued the prescription drug order, or another practitioner responsible for the patient's care, to obtain authorization to refill the prescription;

(4) the drug is essential to sustain the life of the patient or to continue therapy for a chronic condition;

(5) failure to dispense the drug to the patient would result in harm to the health of the patient; and

(6) the drug is not a controlled substance listed in section 152.02, subdivisions 3 to 6, except for a controlled substance that has been specifically prescribed to treat a seizure disorder, in which case the pharmacist may dispense up to a 72-hour supply.

(b) If the conditions in paragraph (a) are met, the amount of the drug dispensed by the pharmacist to the patient must not exceed a 30-day supply, or the quantity originally prescribed, whichever is less, except as provided for controlled substances in paragraph (a), clause (6). If the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold must not exceed the standard unit of dispensing.

(c) A pharmacist shall not dispense or sell the same drug to the same patient, as provided in this section, more than one time in any 12-month period.

(d) A pharmacist must notify the practitioner who issued the prescription drug order not later than 72 hours after the drug is sold or dispensed. The pharmacist must request and receive authorization before any additional refills may be dispensed. If the practitioner declines to provide authorization for additional refills, the pharmacist must inform the patient of that fact.

(e) The record of a drug sold or dispensed under this section shall be maintained in the same manner required for prescription drug orders under this section.

Sec. 9. **[214.122] INFORMATION PROVISION; PHARMACEUTICAL ASSISTANCE PROGRAMS.**

(a) The Board of Medical Practice and the Board of Nursing shall at least annually inform licensees who are authorized to prescribe prescription drugs of the availability of the Board of Pharmacy's website that contains information on resources and programs to assist patients with the cost of prescription drugs. The boards shall provide licensees with the website address established by the Board of Pharmacy under section 151.06, subdivision 6, and the materials described under section 151.06, subdivision 6, paragraph (b).

(b) Licensees must make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website established by the Board of Pharmacy under section 151.06, subdivision 6.