SENATE
STATE OF MINNESOTA
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S.F. No. 2801

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DATE	D-PG	OFFICIAL STATUS
03/01/2018	6230	Introduction and first reading Referred to Health and Human Services Finance and Policy

A bill for an act

relating to health care; establishing the Prescription Drug Cost Review and Rate Setting Act; creating a prescription drug cost review commission and rate-setting requirements; requiring a report; appropriating money; proposing coding for new law in Minnesota Statutes, chapter 62J.

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

Section 1. **[62J.85] CITATION.**

Sections 62J.85 to 62J.94 may be cited as the "Prescription Drug Cost Review and Rate Setting Act."

Sec. 2. **[62J.86] DEFINITIONS.**

Subdivision 1. **Definitions.** For the purposes of sections 62J.85 to 62J.94, the following terms have the meanings given them.

Subd. 2. **Advisory council.** "Advisory council" means the Prescription Drug Cost Review Advisory Council established under section 62J.88.

Subd. 3. **Commission.** "Commission" means the Prescription Drug Cost Review Commission established under section 62J.87.

Subd. 4. **Excess costs.** "Excess costs" means the cost of a prescription drug product that either:

(1) exceeds the therapeutic benefit relative to other therapeutic options or alternative treatments; or

(2) is not sustainable to public and private health care systems over a ten-year time period.

Subd. 5. **Group purchaser.** "Group purchaser" has the meaning given in section 62J.03, subdivision 6, and includes pharmacy benefit managers.

Subd. 6. **Wholesale acquisition cost or WAC.** "Wholesale acquisition cost" or "WAC" has the meaning given in United States Code, title 42, section 1395W-3a(c)(6)(B).

Sec. 3. **[62J.87] PRESCRIPTION DRUG COST REVIEW COMMISSION.**

Subdivision 1. **Establishment.** The Prescription Drug Cost Review Commission is created to protect consumers, state and local governments, health plan companies, providers, pharmacies, and other health care system stakeholders from excessive costs of certain prescription drugs.

Subd. 2. **Membership.** (a) The Prescription Drug Cost Review Commission consists of seven members appointed as follows:

(1) three members appointed by the governor;

(2) one member appointed by the majority leader of the senate;

(3) one member appointed by the minority leader of the senate;

(4) one member appointed by the speaker of the house of representatives; and

(5) one member appointed by the minority leader of the house of representatives.

(b) All members appointed must have knowledge and demonstrated expertise in health care economics and finance.

(c) Initial appointments shall be made by January 1, 2019. Initial appointees shall serve staggered terms of two, three, or four years as determined by lot by the secretary of state.

Subd. 3. **Terms.** (a) Following the initial appointments, commission appointees shall serve four-year terms and shall serve no more than two consecutive terms.

(b) A commission member may resign at any time by giving written notice to the commission.

Subd. 4. **Chair; other officers.** (a) The governor shall designate an acting chair from the members appointed by the governor.

(b) The commission shall elect a chair to replace the acting chair at the first meeting of the commission by a majority of the members. The chair shall serve for one year.

(c) The commission shall elect a vice-chair and other officers from its membership as it deems necessary.

Subd. 5. **Staff; technical assistance.** (a) The commission may hire an executive director who serves in the unclassified service and may employ or contract with professional and technical assistance as the commission deems necessary to perform the commission's duties.

(b) The attorney general shall provide legal services to the commission.

Subd. 6. **Meetings.** (a) The commission shall meet publicly at least every three months to review prescription drug product information submitted to the commission under section 62J.90. If there are no pending submissions, the chair of the commission may cancel or postpone the required meeting.

(b) The commission shall announce each public meeting at least two weeks prior to the scheduled date of the meeting. Any materials for the meeting shall be made public at least one week prior to the scheduled date of the meeting.

(c) At each public meeting, the commission shall provide the opportunity for comments from the public, including the opportunity for written comments to be submitted to the commission prior to a decision by the commission.

Sec. 4. **[62J.88] PRESCRIPTION DRUG COST REVIEW ADVISORY COUNCIL.**

Subdivision 1. **Establishment.** The governor shall appoint an 11-member stakeholder advisory council to provide advice to the commission on drug cost issues and to represent stakeholders' views. The members of the advisory council shall be appointed based on their knowledge and demonstrated expertise in one or more of the following areas: the pharmaceutical business; practice of medicine; patient perspectives; health care cost trends and drivers; clinical and health services research; and the health care marketplace.

Subd. 2. **Membership.** The council's membership shall consist of the following:

(1) two members representing patients and health care consumers;

(2) two members representing health care providers;

(3) one member representing health plan companies;

(4) two members representing employers, with one member representing large employers and one member representing small employers;

(5) one member representing government employee benefit plans;

(6) one member representing pharmaceutical manufacturers;

(7) one member who is a health services clinical researcher; and

(8) one member who is a pharmacologist.

Subd. 3. **Terms.** (a) The initial appointments to the advisory council shall be made by January 1, 2019. The initial appointed advisory council members shall serve staggered terms of two, three, or four years determined by lot by the secretary of state. Following the initial appointments, the advisory council members shall serve four-year terms.

(b) Removal and vacancies of advisory council members shall be governed by section 15.059.

Subd. 4. **Compensation.** Advisory council members may be compensated according to section 15.059.

Subd. 5. **Exemption.** Notwithstanding section 15.059, the advisory council shall not expire.

Sec. 5. **[62J.89] CONFLICTS OF INTEREST.**

Subdivision 1. **Definition.** For purposes of this section, "conflict of interest" means a financial or personal association that has the potential to bias or have the appearance of biasing a person's decisions in matters related to the commission or in the conduct of the commission's activities. A conflict of interest includes any instance in which a person or a person's immediate family member, including a spouse, parent, child, or other legal dependent, has received or could receive a direct or indirect financial benefit of any amount deriving from the result or findings of a decision or determination of the commission.

Subd. 2. **General.** (a) Prior to the acceptance of an appointment or employment, or prior to entering into a contractual agreement, a commission or advisory council member, commission staff member, or third-party contractor must disclose to the appointing authority or the commission any conflicts of interest. The information disclosed shall include the type, nature, and magnitude of the interests involved.

(b) A commission member, advisory council member, commission staff member, or third-party contractor with a conflict of interest with regard to any prescription drug product under review must recuse themselves from any discussion, review, decision, or determination made by the commission relating to the prescription drug product.

Subd. 3. **Prohibitions.** Commission members, advisory council members, commission staff, or third-party contractors are prohibited from accepting gifts, bequeaths, or donations

of services or property that raise the specter of a conflict of interest or have the appearance of injecting bias into the activities of the commission.

Sec. 6. **[62J.90] REQUIRED MANUFACTURER NOTICE.**

Subdivision 1. **Patented products.** (a) A drug manufacturer shall notify the commission if the manufacturer:

(1) plans to increase the WAC of a patent-protected brand name drug by more than $10,000 during any 12-month period; or

(2) intends to introduce to market a brand name drug that has a WAC of $30,000 per year or per course of treatment.

(b) The notice must be provided in writing to the commission at least 30 days prior to the planned effective date of the increase or introduction and must include a justification as described under subdivision 4.

Subd. 2. **Generic products and off-patent sole-source brand products.** (a) A drug manufacturer shall notify the commission if the manufacturer:

(1) plans to increase the WAC of a generic or off-patent sole-source brand product drug by more than 25 percent or by more than $300 during any 12-month period; or

(2) intends to introduce to market a generic drug that has a WAC of $3,000 or more annually.

(b) The notice must be provided in writing to the commission at least 30 days prior to the planned effective date of the increase or introduction and must include a justification as described under subdivision 4.

Subd. 3. **Other price increase notifications.** (a) After consultation with the advisory council, the commission may establish a third threshold for brand name prescription drugs and generic and off-patent, sole-source brand prescription drugs that when breached shall require the drug manufacturer of the drug product to notify the commission according to this section. This third threshold may require reporting of price increases that are below the thresholds specified under subdivisions 1 and 2, but impose costs on the state's public and private health care systems that create significant challenges to affordability.

(b) If the commission establishes a third threshold, the commission shall notify the legislature of the threshold and the specific triggers of the threshold.

Subd. 4. **Justification.** A drug manufacturer shall include in the notice required to be submitted to the commission under subdivision 1, 2, or 3 a justification for the proposed

introduction price or price increase. The justification must include all documents and research related to the manufacturer's selection of the introduction price or price increase, including but not limited to:

(1) life cycle management;

(2) net average price in Minnesota that includes the net of all price concessions, such as discounts and rebates, but excludes in-kind concessions;

(3) market competition and context;

(4) projected revenue; and

(5) if available, estimated value or cost-effectiveness of the prescription drug product.

Subd. 5. **Additional information.** Upon receiving the justification response required under this subdivision, the commission may make a written request to the manufacturer for additional information. The commission shall require the manufacturer to submit any additional information by a specific date, taking into consideration the request and its complexity for the manufacturer to fulfill.

Subd. 6. **Public data.** The commission shall make available to the public all notifications and justifications received by the commission under this section, unless the information is likely to compromise the financial or competitive position of the manufacturer or could qualify as a trade secret.

Sec. 7. **[62J.91] DETERMINATION TO PROCEED WITH A FULL COST REVIEW.**

(a) The commission shall make a determination as to whether to undertake a full cost review of a prescription drug that triggered the notification requirements under section 62J.90. The commission shall publicly meet and deliberate on whether to subject a prescription drug product to a full cost review and shall consider any public comments received prior to making its decision.

(b) Any member of the commission may request a vote on whether or not to undertake a full cost review under section 62J.92 if there is not a consensus of the commission with the decision.

(c) The commission shall provide the public with the opportunity to request that the commission conduct a full cost review of any of the prescription drug products that triggered the notification requirements under section 62J.90.

Sec. 8. **[62J.92] COST REVIEW; DETERMINING EXCESS COSTS.**

Subdivision 1. **General.** (a) Once a decision by the commission has been made to proceed with a full cost review, the commission shall conduct the review and make a determination as to whether appropriate utilization of the prescription drug under review, based on utilization that is consistent with the United States Food and Drug Administration (FDA) label, has led or will lead to excess costs.

(b) The commission shall accept analysis and data from manufacturers, group purchasers, consumers, and experts, staff, or third-party contractors to determine if the cost to the health care system of appropriate utilization is commensurate with a benefit to the system, and whether the drug under review is affordable for state residents.

(c) If the commission finds that the cost is excessive and not affordable, the commission shall establish a cost or payment rate for the drug by which all group purchasers, pharmacies, and wholesale drug distributors must abide. No group purchaser, pharmacy, or wholesale distributor shall pay more for any prescription drug product for which the commission established a rate according to section 62J.93.

Subd. 2. **Phase-one determination.** In reviewing the cost of a prescription drug, the commission may consider the following factors:

(1) the price at which the prescription drug has been and will be sold in the state;

(2) the average monetary price concession, including any discounts or rebates, the manufacturer provides to a group purchaser or is expected to provide to a group purchaser as reported by the manufacturer and the group purchaser;

(3) the price at which therapeutic alternatives have been or will be sold in the state;

(4) the average monetary price concession, discount, or rebate the manufacturer provides or is expected to provide to a group purchaser for therapeutic alternatives;

(5) the relative clinical merits of the prescription drug product under review compared to therapeutic alternatives;

(6) the cost to group purchasers based on patient access consistent with FDA labeled indications;

(7) the impact on patient access resulting from cost of the prescription drug relative to insurance benefit design;

(8) the current or expected value of manufacturer-supported, drug-specific, patient access programs;

(9) the relative financial impacts to health, medical, and other social services costs that may be quantified and compared to baseline effects of existing therapeutic alternatives; and

(10) other factors that may be specified by the commission.

Subd. 3. **Phase-two determination.** If, after considering the factors described in subdivision 2, the commission is unable to determine if a prescription drug product will produce or has produced excess costs, the commission may consider the following:

(1) manufacturer research and development costs, as shown on the manufacturer's federal tax filing for the most recent tax year multiplied by the proportion of manufacturer in-state sales to United States sales;

(2) that portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer in-state sales to total manufacturer United States sales for the product under review;

(3) gross and net manufacturer revenues for the most recent tax years; and

(4) any additional factors that can be specified in regulations or that the commission considers relevant to the circumstances, as may be proposed by the drug manufacturer.

Subd. 4. **Public deliberation.** (a) The commission shall publicly review a prescription drug product cost analysis and take a public vote on whether to impose a cost or payment limit on the prescription drug product according to section 62J.93.

(b) All submissions to the commission pertaining to a cost review shall be public with the exception of information determined to be proprietary to the persons submitting the information. The commission shall establish parameters for what is considered proprietary and shall give attention to any premarket submissions.

Sec. 9. **[62J.93] DETERMINATIONS; COMPLIANCE; REMEDIES.**

Subdivision 1. **Rate setting.** In the event the commission finds that the spending on a prescription drug product under review creates excess costs, the commission shall establish the level of reimbursement that must be billed and paid among:

(1) group purchasers and pharmacies;

(2) wholesale distributors and pharmacies; and

(3) pharmacies and uninsured consumers or consumers who are enrolled in a health plan but who have not yet met the health plan's deductible.

Subd. 2. **Compliance with rate setting.** (a) Instances of failure to bill and pay at the rate established by the commission under this section shall be referred to the attorney general for possible action.

(b) Upon a finding of noncompliance with the commission's requirements, the attorney general may pursue remedies consistent with chapter 8, or in the case of intentional profiteering, appropriate criminal charges.

(c) A health care stakeholder who obtains price concessions from a drug manufacturer that result in a lower net cost to the stakeholder than the rate established by the commission is not considered noncompliant.

Subd. 3. **Compliance with reporting.** Failure of a drug manufacturer to report to the commission as required by section 62J.90, or submit any information requested by the commission under sections 62J.86 to 62J.94, shall be referred to the attorney general for review and possible action as permitted under chapter 8.

Subd. 4. **Appeals.** (a) Persons affected by a decision of the commission may request an appeal of the commission's decision within 30 days of the decision. The commission shall hear the appeal and render a decision within 60 days of the appeal request.

(b) All appeal decisions are subject to judicial review.

Sec. 10. **[62J.94] REPORTS.**

Beginning March 1, 2020, the commission shall annually report to the governor and legislature on general prescription drug price trends, the number of manufacturers required to report during the prior calendar year under section 62J.90, and the number of prescription drug products that were subject to the commission's cost review and analysis, including the result of any analysis as well as the number and disposition of appeals and judicial reviews.

Sec. 11. **FINANCING RECOMMENDATIONS.**

By March 1, 2019, the Prescription Drug Cost Review Commission shall submit recommendations to the legislature on possible financing options for the commission beginning fiscal year 2020, to ensure ongoing financing for the commission and the implementation of the Prescription Drug Cost Review and Rate Setting Act.

Sec. 12. **APPROPRIATION.**

$..... in fiscal year 2019 is appropriated from the general fund to the commissioner of health for the Prescription Drug Cost Review Commission established under Minnesota

Statutes, section 62J.88, and the implementation of the Prescription Drug Cost Review and Rate Setting Act.