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STATE OF MINNESOTA
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S.F. No. 3120

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02/13/2020	4754	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 Affordability Act; creating a prescription drug affordability commission and prescription drug affordability requirements; requiring a report; 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.95 may be cited as the "Prescription Drug Affordability Act."

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

Subdivision 1. **Definitions.** For the purposes of sections 62J.85 to 62J.95, the following terms have the meanings given them.

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

Subd. 3. **Biologic.** "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under Code of Federal Regulations, title 42, section 447.502.

Subd. 4. **Biosimilar.** "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under Code of Federal Regulations, title 42, section 262(k)(3).

Subd. 5. **Brand name drug.** "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under United

States Code, title 21, section 355(c). This definition does not include an authorized generic as defined by Code of Federal Regulations, title 42, section 447.502.

Subd. 6. **Commission.** "Commission" means the Prescription Drug Affordability Commission established under section 62J.87.

Subd. 7. **Generic drug.** "Generic drug" means:

(1) a retail drug that is marketed or distributed in accordance with an abbreviated new drug application approved under United States Code, title 21, section 355(j);

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

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

Subd. 8. **Group purchaser.** "Group purchaser" has the meaning given in section 62J.03, subdivision 6, and includes pharmacy benefit managers as defined in section 62W.02, subdivision 15.

Subd. 9. **Manufacturer.** "Manufacturer" means an entity that:

(1) engages in the manufacture of a prescription drug product or enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(2) sets or changes the wholesale acquisition cost of the prescription drug product it manufacturers or markets.

Subd. 10. **Prescription drug product.** "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

Subd. 11. **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 AFFORDABILITY COMMISSION.**

Subdivision 1. **Establishment.** The Prescription Drug Affordability 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 Affordability 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; 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. A member must not be an employee of, a board member of, or a consultant to a manufacturer or trade association for manufacturers.

(c) Initial appointments shall be made by January 1, 2021. 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. **Compensation.** The commission members shall not receive compensation but may receive reimbursement for expenses as authorized under section 15.059, subdivision 3.

Subd. 7. **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. The commission may meet in closed session when reviewing

proprietary information as determined under the standards developed in accordance with section 62J.91, subdivision 4.

(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.

Subd. 8. **Expiration.** Notwithstanding any law to the contrary, the commission shall not expire.

Sec. 4. **[62J.88] PRESCRIPTION DRUG AFFORDABILITY 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, 2021. 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, the advisory council, or in the conduct of the commission's or council'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. For purposes of this section, a financial benefit includes honoraria, fees, stock, the value of the member's or the immediate family member's stock holdings, and any direct financial benefit deriving from the finding of a review conducted under sections 62J.85 to 62J.95.

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.

(c) Any conflict of interest must be disclosed in advance of the first meeting after the conflict is identified or within five days after the conflict is identified, whichever is earlier.

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 REPORTING REQUIREMENT.**

Subdivision 1. **Brand name drugs or biologics.** A drug manufacturer shall notify the commission if the manufacturer:

(1) increases the WAC of a brand name drug or biologic by more than ten percent or by more than $10,000 during any 12-month period or course of treatment if less than 12 months; or

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

Subd. 2. **Biosimilar drugs.** A drug manufacturer shall notify the commission if the manufacturer intends to introduce to market a biosimilar at a WAC that is not at least 15 percent lower than the referenced brand biologic at the time the biosimilar is introduced.

Subd. 3. **Generic drugs.** A drug manufacturer shall notify the commission if the manufacturer:

(1) increases the WAC of a generic drug by $100 or more for:

(i) a 30-day supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration (FDA);

(ii) a supply lasting a patient for fewer than 30 days based on recommended dosage approved for labeling by the FDA; or

(iii) one unit of the drug if the labeling approved by the FDA does not recommend a finite dosage; and

(2) the WAC is increased by 200 percent or more during the immediate preceding 12-month period, as determined by the difference between the resulting WAC and the average of the WAC reported over the preceding 12 months.

Subd. 4. **Other reporting requirements.** The commission, in consultation with the advisory council, may establish a reporting threshold for manufacturers for other prescription drug products that may impose costs that create significant affordability challenges for the state health care system or for patients.

Subd. 5. **Notification; justification.** (a) The notice provided by the manufacturer under subdivisions 1 to 4 must be provided to the commission in writing at least 30 days before the planned effective date of the increase or the introduction of the drug to market. Upon

the receipt of the notification, the commission shall review the justification for the introductory price or price increase of the prescription drug product reported.

(b) To the extent practicable, the commission shall access manufacturer justification information made public by other states.

(c) If manufacturer justification information is not available from other state sources, the commission may require a manufacturer to submit to the commission any documents and research related to the manufacturer's selection of the introductory 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. 6. **Public input.** (a) 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.

(b) The commission shall allow the public to request the commission to proceed to a cost review of any prescription drug product reported under this section.

Subd. 7. **Determination to proceed with review.** (a) The commission may initiate a review of the cost of a prescription drug product reported to the commission under this section.

(b) The commission shall also review any public request made under subdivision 6, paragraph (b), and shall determine whether to initiate a review of the cost of the prescription drug product identified in the request.

(c) If there is not consensus among the members of the commission on whether or not to review a prescription drug product, any member of the commission may request a vote to determine whether or not to review the prescription drug product.

Sec. 7. **[62J.91] AFFORDABILITY OF A PRESCRIPTION DRUG PRODUCT.**

Subdivision 1. **General.** Once a decision by the commission has been made to proceed with a cost review of a prescription drug product, 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 and standard medical practice, has led or will lead to affordability challenges for the state health care system or for patients.

Subd. 2. **Review considerations.** In reviewing the cost of a prescription drug product, the commission may consider the following factors:

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

(2) the average monetary price concession, discount, or rebate the manufacturer provides to a group purchaser in this state as reported by the manufacturer and the group purchaser expressed as a percent of the WAC for prescription drug product under review;

(3) the total amount of the concession, discount, or rebate the manufacturer provides to each pharmacy benefit manager operating in the state for the prescription drug product under review, expressed as a percent of the wholesale acquisition cost;

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

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

(6) the cost to group purchasers based on patient access consistent with the United States Food and Drug Administration (FDA) labeled indications;

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

(8) the current or expected dollar value of drug-specific patient access programs that are supported by manufacturers;

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

(10) the average patient co-pay or other cost-sharing for the prescription drug product in the state;

(11) any information a manufacturer chooses to provide; and

(12) any other factors as determined by the commission.

Subd. 3. **Further review factors.** If, after considering the factors described in subdivision 2, the commission is unable to determine whether a prescription drug product will produce or has produced an affordability challenge using the factors described in subdivision 2, the commission may consider the following factors:

(1) manufacturer research and development costs, as indicated on the manufacturer's federal tax filing for the most recent tax year in proportion to the manufacturer's sales in the state;

(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 sales in the United States for the product under review;

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

(4) any additional factors as determined by the commission to be relevant to the circumstance.

Subd. 4. **Public data; proprietary information.** (a) Any submission made to the commission related to a drug cost review shall be made available to the public with the exception of information determined by the commission to be proprietary.

(b) The commission shall establish the standards for the information to be considered proprietary under paragraph (a), including standards for heightened consideration of proprietary information for submissions for a cost review of a drug that is not yet approved by the FDA.

(c) Prior to the commission establishing the standards under paragraph (b), the public shall be provided notice and the opportunity to submit comments.

Sec. 8. **[62J.92] DETERMINATIONS; COMPLIANCE; REMEDIES.**

Subdivision 1. **Maximum reimbursement level.** (a) In the event the commission finds that the spending on a prescription drug product reviewed under section 62J.91 creates an affordability challenge for the health care system or for patients, the commission shall establish a maximum reimbursement level after considering:

(1) the cost of administering the drug;

(2) the cost of delivering the drug to consumers; and

(3) any other relevant administrative costs related to the drug.

(b) The maximum reimbursement level shall apply to all public and private purchases, payments, and payer reimbursements for the prescription drug product that is intended for individuals in the state in person, by mail, or by other means.

(c) The commission shall determine how each participant in the supply chain of the prescription drug shall be remunerated.

Subd. 2. **Noncompliance.** (a) The noncompliance of an entity to bill or pay a reimbursement rate in accordance with the level established by the commission under this section shall be referred to the Office of the Attorney General.

(b) If the Office of the Attorney General finds that an entity was noncompliant with the commission reimbursement requirements, the attorney general may pursue remedies consistent with chapter 8 or appropriate criminal charges if there is evidence of intentional profiteering.

(c) An entity who obtains price concessions from a drug manufacturer that result in a lower net cost to the stakeholder than the maximum level established by the commission shall not be considered to be in noncompliance.

(d) The Office of the Attorney General shall provide guidance to stakeholders concerning activities that could be considered noncompliant that are in addition to billing and payment where drug costs exceed the level established by the commission.

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.95, 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 date of the decision. The commission shall hear the appeal and render a decision within 60 days of the hearing.

(b) All appeal decisions are subject to judicial review in accordance with chapter 14.

Sec. 9. **[62J.93] REPORTS.**

Beginning March 1, 2021, and each March 1 thereafter, the commission shall submit a report to the governor and legislature on general price trends for prescription drug products, 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. 10. **[62J.94] ERISA PLANS AND MEDICARE DRUG PLANS.**

(a) Nothing in sections 62J.85 to 62J.95 shall be construed to require ERISA plans or Medicare Part D plans to comply with decisions of the commission, but are free to choose to reimburse more than the maximum reimbursement level established by the commission under section 62J.92.

(b) Providers who dispense and administer drugs in the state must bill all payers no more than the maximum reimbursement level without regard to whether or not an ERISA plan or Medicare Part D plan chooses to reimburse the provider in an amount greater than the maximum reimbursement level limit established by the commission.

(c) For purposes of this section, an ERISA plan or group health plan is an employee welfare benefit plan established by or maintained by an employer or an employee organization, or both, that provides employer sponsored health coverage to employees and the employee's dependents and is subject to the Employee Retirement Income Security Act of 1974 (ERISA).

Sec. 11. **[62J.95] SEVERABILITY.**

If any provision of sections 62J.85 to 62J.94 or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of sections 62J.85 to 62J.94 that can be given effect without the invalid provision or application.

Sec. 12. **FINANCING RECOMMENDATIONS.**

By March 1, 2021, the Prescription Drug Affordability Commission established under Minnesota Statutes, section 62J.87, shall submit recommendations to the legislature on possible financing options for the commission beginning fiscal year 2022, to ensure ongoing financing for the commission and the implementation of the Prescription Drug Affordability Act.

Sec. 13. **APPROPRIATION.**

$..... in fiscal year 2021 is appropriated from the general fund to the commissioner of health for the Prescription Drug Affordability Commission established under Minnesota Statutes, section 62J.87, and the implementation of the Prescription Drug Affordability Act.