SENATE
STATE OF MINNESOTA
NINETY-SECOND SESSION

S.F. No. 1121

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DATE	D-PG	OFFICIAL STATUS
02/17/2021		Introduction and first reading
		Referred to Health and Human Services Finance and Policy

A bill for an act

relating to health; establishing a prescription drug affordability board and prescription drug affordability advisory council; providing for prescription drug cost reviews and remedies; 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.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" has the meaning provided in section 62J.84, subdivision 2, paragraph (b).

Subd. 5. **Board.** "Board" means the Prescription Drug Affordability Board established under section 62J.87.

Subd. 6. **Brand name drug.** "Brand name drug" has the meaning provided in section 62J.84, subdivision 2, paragraph (c).

Subd. 7. **Generic drug.** "Generic drug" has the meaning provided in section 62J.84, subdivision 2, paragraph (e).

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 BOARD.**

Subdivision 1. **Establishment.** The Prescription Drug Affordability Board is created as a board under section 15.012, paragraph (a), to protect consumers, state and local governments, health plan companies, providers, pharmacies, and other health care system stakeholders from unaffordable costs of certain prescription drugs.

Subd. 2. **Membership.** (a) The Prescription Drug Affordability Board 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 pharmaceutical economics and finance or 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 or a pharmacy benefit manager or trade association for pharmacy benefit managers.

(c) Initial appointments shall be made by January 1, 2022.

Subd. 3. **Terms.** (a) Board appointees shall serve four-year terms, except that initial appointees shall serve staggered terms of two, three, or four years as determined by lot by the secretary of state. A board member shall serve no more than two consecutive terms.

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

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

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

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

Subd. 5. **Staff; technical assistance.** (a) The board shall hire an executive director and other staff, who shall serve in the unclassified service. The executive director must have knowledge and demonstrated expertise in pharmacoeconomics, pharmacology, health policy, health services research, medicine, or a related field or discipline. The board may employ or contract for professional and technical assistance as the board deems necessary to perform the board's duties.

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

Subd. 6. **Compensation.** The board members shall not receive compensation but may receive reimbursement for expenses as authorized under section 15.059, subdivision 3.

Subd. 7. **Meetings.** (a) Meetings of the board are subject to chapter 13D. The board shall meet publicly at least every three months to review prescription drug product information submitted to the board under section 62J.90. If there are no pending submissions, the chair of the board may cancel or postpone the required meeting. The board 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 board 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 board shall provide the opportunity for comments from the public, including the opportunity for written comments to be submitted to the board prior to a decision by the board.

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 board 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;

(8) one member who is a pharmacologist; and

(9) one member representing the commissioner of health with expertise in health economics.

Subd. 3. **Terms.** (a) The initial appointments to the advisory council shall be made by January 1, 2022. 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 board, the advisory council, or in the conduct of the board's or council's activities. A conflict of interest includes any instance in which a person, a person's immediate family member, including a spouse, parent, child, or other legal dependent, or an in-law of any of the preceding individuals, 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 board. For purposes of this section, a financial benefit includes honoraria, fees, stock, the value of the member's, immediate family member's, or in-law'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 board or advisory council member, board staff member, or third-party contractor must disclose to the appointing authority or the board any conflicts of interest. The information disclosed shall include the type, nature, and magnitude of the interests involved.

(b) A board member, board 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 board 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.** Board members, board 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 board.

Sec. 6. **[62J.90] PRESCRIPTION DRUG PRICE INFORMATION; DECISION TO CONDUCT COST REVIEW.**

Subdivision 1. **Drug price information from the commissioner of health and other sources.** (a) The commissioner of health shall provide to the board the information reported to the commissioner by drug manufacturers under section 62J.84, subdivisions 3, 4, and 5. The commissioner shall provide this information to the board within 30 days of the date the information is received from drug manufacturers.

(b) The board shall subscribe to one or more prescription drug pricing files, such as Medispan or FirstDatabank, or as otherwise determined by the board.

Subd. 2. **Identification of certain prescription drug products.** (a) The board, in consultation with the advisory council, shall identify the following prescription drug products:

(1) brand name drugs or biologics for which the WAC increases 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, after adjusting for changes in the consumer price index (CPI);

(2) brand name drugs or biologics that have been introduced at a WAC of $30,000 per calendar year or per course of treatment;

(3) biosimilar drugs that have been introduced at a WAC that is not at least 15 percent lower than the referenced brand name biologic at the time the biosimilar is introduced; and

(4) generic drugs for which the WAC:

(i) is $100 or more, after adjusting for changes in the consumer price index (CPI), for:

(A) 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);

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

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

(ii) 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, after adjusting for changes in the consumer price index (CPI).

(b) The board, in consultation with the advisory council, shall identify prescription drug products not described in paragraph (a) that may impose costs that create significant affordability challenges for the state health care system or for patients, including but not limited to drugs to address public health emergencies.

(c) The board shall make available to the public the names and related price information of the prescription drug products identified under this subdivision, with the exception of information determined by the board to be proprietary under the standards developed by the board under section 62J.91, subdivision 4.

Subd. 3. **Determination to proceed with review.** (a) The board may initiate a cost review of a prescription drug product identified by the board under this section.

(b) The board shall consider requests by the public for the board to proceed with a cost review of any prescription drug product identified under this section.

(c) If there is no consensus among the members of the board on whether or not to initiate a cost review of a prescription drug product, any member of the board may request a vote to determine whether or not to review the cost of the prescription drug product.

Sec. 7. **[62J.91] PRESCRIPTION DRUG PRODUCT REVIEWS.**

Subdivision 1. **General.** Once a decision by the board has been made to proceed with a cost review of a prescription drug product, the board 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 or 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 board 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 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 in the state or is expected to provide to group purchasers in the state for therapeutic alternatives;

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

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

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

(8) 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;

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

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

(11) any other factors as determined by the board.

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

(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;

(4) any information and research related to the manufacturer's selection of the introductory price or price increase, including but not limited to:

(i) life cycle management;

(ii) market competition and context; and

(iii) projected revenue; and

(5) any additional factors determined by the board to be relevant.

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

(b) The board shall establish the standards for the information to be considered proprietary under paragraph (a) and section 62J.90, subdivision 2, 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 board 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. **Upper payment limit.** (a) In the event the board finds that the spending on a prescription drug product reviewed under section 62J.91 creates an affordability challenge for the state health care system or for patients, the board shall establish an upper payment limit after considering:

(1) the cost of administering the drug;

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

(3) the range of prices at which the drug is sold in the United States according to one or more pricing files accessed under section 62J.90, subdivision 1, and the range at which pharmacies are reimbursed in Canada; and

(4) any other relevant pricing and administrative cost information for the drug.

(b) The upper payment limit 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.

Subd. 2. **Noncompliance.** (a) The failure of an entity to comply with an upper payment limit established by the board 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 upper payment limit 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 upper payment limit established by the board shall not be considered to be in noncompliance.

(d) The Office of the Attorney General may provide guidance to stakeholders concerning activities that could be considered noncompliant.

Subd. 3. **Appeals.** (a) Persons affected by a decision of the board may request an appeal of the board's decision within 30 days of the date of the decision. The board 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, 2022, and each March 1 thereafter, the board shall submit a report to the governor and legislature on general price trends for prescription drug products and the number of prescription drug products that were subject to the board'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 board, but are free to choose to exceed the upper payment limit established by the board under section 62J.92.

(b) Providers who dispense and administer drugs in the state must bill all payers no more than the upper payment limit 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 upper payment limit established by the board.

(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. **APPROPRIATION.**

$..... for the biennium beginning July 1, 2021, is appropriated from the general fund to the Prescription Drug Affordability Board established under Minnesota Statutes, section 62J.87, for implementation of the Prescription Drug Affordability Act.