SENATE
STATE OF MINNESOTA
NINETY-THIRD SESSION

S.F. No. 168

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DATE	D-PG	OFFICIAL STATUS
01/11/2023	142	Introduction and first reading Referred to Health and Human Services
01/19/2023	309	Author added Boldon
01/25/2023	383	Withdrawn and re-referred to Commerce and Consumer Protection
01/27/2023	468	Author added Fateh
02/06/2023	685	Author added Hoffman
02/27/2023		Comm report: To pass as amended and re-refer to Judiciary and Public Safety

A bill for an act

relating to health; prohibiting excessive price increases by manufacturers to generic or off-patent drugs; authorizing the attorney general to take action against manufacturers for certain price increases; prohibiting withdrawal of certain generic or off-patent drugs sales; establishing a prescription drug affordability board and prescription drug affordability advisory council; providing for prescription drug cost reviews and remedies; providing appointments; imposing civil penalties; requiring a report; appropriating money; amending Minnesota Statutes 2022, section 151.071, subdivisions 1, 2; proposing coding for new law in Minnesota Statutes, chapter 62J.

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

Section 1. **[62J.841] DEFINITIONS.**

Subdivision 1. **Scope.** For purposes of sections 62J.841 to 62J.845, the following definitions apply.

Subd. 2. **Consumer Price Index.** "Consumer Price Index" means the Consumer Price Index, Annual Average, for All Urban Consumers, CPI-U: U.S. City Average, All Items, reported by the United States Department of Labor, Bureau of Labor Statistics, or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "Consumer Price Index" means a comparable index chosen by the Bureau of Labor Statistics.

Subd. 3. **Generic or off-patent drug.** "Generic or off-patent drug" means any prescription drug for which any exclusive marketing rights granted under the Federal Food, Drug, and Cosmetic Act, section 351 of the federal Public Health Service Act, and federal patent law have expired, including any drug-device combination product for the delivery of a generic drug.

Subd. 4. **Manufacturer.** "Manufacturer" has the meaning provided in section 151.01, subdivision 14a.

Subd. 5. **Prescription drug.** "Prescription drug" means a drug for human use subject to United States Code, title 21, section 353(b)(1).

Subd. 6. **Wholesale acquisition cost.** "Wholesale acquisition cost" has the meaning provided in United States Code, title 42, section 1395w-3a.

Subd. 7. **Wholesale distributor.** "Wholesale distributor" has the meaning provided in section 151.441, subdivision 14.

Sec. 2. **[62J.842] EXCESSIVE PRICE INCREASES PROHIBITED.**

Subdivision 1. **Prohibition.** No manufacturer shall impose, or cause to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state.

Subd. 2. **Excessive price increase.** A price increase is excessive for purposes of this section when:

(1) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds:

(i) 15 percent of the wholesale acquisition cost over the immediately preceding calendar year; or

(ii) 40 percent of the wholesale acquisition cost over the immediately preceding three calendar years; and

(2) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds $30 for:

(i) a 30-day supply of the drug; or

(ii) a course of treatment lasting less than 30 days.

Subd. 3. **Exemption.** It is not a violation of this section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug.

Sec. 3. **[62J.843] REGISTERED AGENT AND OFFICE WITHIN THE STATE.**

Any manufacturer that sells, distributes, delivers, or offers for sale any generic or off-patent drug in the state must maintain a registered agent and office within the state.

Sec. 4. **[62J.844] ENFORCEMENT.**

Subdivision 1. **Notification.** The commissioner of management and budget and any other state agency that provides or purchases a pharmacy benefit except the Department of Human Services, and any entity under contract with a state agency to provide a pharmacy benefit other than an entity under contract with the Department of Human Services, shall notify the manufacturer of a generic or off-patent drug, the attorney general, and the Board of Pharmacy of any price increase that the commissioner or entity believes may violate section 62J.842.

Subd. 2. **Submission of drug cost statement and other information by manufacturer; investigation by attorney general.** (a) Within 45 days of receiving a notice under subdivision 1, the manufacturer of the generic or off-patent drug shall submit a drug cost statement to the attorney general. The statement must:

(1) itemize the cost components related to production of the drug;

(2) identify the circumstances and timing of any increase in materials or manufacturing costs that caused any increase during the preceding calendar year, or preceding three calendar years as applicable, in the price of the drug; and

(3) provide any other information that the manufacturer believes to be relevant to a determination of whether a violation of section 62J.842 has occurred.

(b) The attorney general may investigate whether a violation of section 62J.842 has occurred, is occurring, or is about to occur, in accordance with section 8.31, subdivision 2.

Subd. 3. **Petition to court.** (a) On petition of the attorney general, a court may issue an order:

(1) compelling the manufacturer of a generic or off-patent drug to:

(i) provide the drug cost statement required under subdivision 2, paragraph (a); and

(ii) answer interrogatories, produce records or documents, or be examined under oath, as required by the attorney general under subdivision 2, paragraph (b);

(2) restraining or enjoining a violation of sections 62J.841 to 62J.845, including issuing an order requiring that drug prices be restored to levels that comply with section 62J.842;

(3) requiring the manufacturer to provide an accounting to the attorney general of all revenues resulting from a violation of section 62J.842;

(4) requiring the manufacturer to repay to all consumers, including any third-party payers, any money acquired as a result of a price increase that violates section 62J.842;

(5) notwithstanding section 16A.151, requiring that all revenues generated from a violation of section 62J.842 be remitted to the state and deposited into a special fund, to be used for initiatives to reduce the cost to consumers of acquiring prescription drugs, if a manufacturer is unable to determine the individual transactions necessary to provide the repayments described in clause (4);

(6) imposing a civil penalty of up to $10,000 per day for each violation of section 62J.842;

(7) providing for the attorney general's recovery of costs and disbursements incurred in bringing an action against a manufacturer found in violation of section 62J.842, including the costs of investigation and reasonable attorney's fees; and

(8) providing any other appropriate relief, including any other equitable relief as determined by the court.

(b) For purposes of paragraph (a), clause (6), every individual transaction in violation of section 62J.842 is considered a separate violation.

Subd. 4. **Private right of action.** Any action brought pursuant to section 8.31, subdivision 3a, by a person injured by a violation of section 62J.842 is for the benefit of the public.

Sec. 5. **[62J.845] PROHIBITION ON WITHDRAWAL OF GENERIC OR OFF-PATENT DRUGS FOR SALE.**

Subdivision 1. **Prohibition.** A manufacturer of a generic or off-patent drug is prohibited from withdrawing that drug from sale or distribution within this state for the purpose of avoiding the prohibition on excessive price increases under section 62J.842.

Subd. 2. **Notice to board and attorney general.** Any manufacturer that intends to withdraw a generic or off-patent drug from sale or distribution within the state shall provide a written notice of withdrawal to the Board of Pharmacy and the attorney general, at least 180 days prior to the withdrawal.

Subd. 3. **Financial penalty.** The attorney general shall assess a penalty of $500,000 on any manufacturer of a generic or off-patent drug that the attorney general determines has failed to comply with the requirements of this section.

Sec. 6. **[62J.846] SEVERABILITY.**

If any provision of sections 62J.841 to 62J.845 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.841 to 62J.845 that can be given effect without the invalid provision or application.

Sec. 7. **[62J.85] CITATION.**

Sections 62J.85 to 62J.95 may be cited as the "Prescription Drug Affordability Act."

Sec. 8. **[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. 9. **[62J.87] PRESCRIPTION DRUG AFFORDABILITY BOARD.**

Subdivision 1. **Establishment.** The Legislative Coordinating Commission shall establish the Prescription Drug Affordability Board, which shall be governed 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 must be made by January 1, 2024.

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. 10. **[62J.88] PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL.**

Subdivision 1. **Establishment.** The governor shall appoint a 12-member stakeholder advisory council to provide advice to the board on drug cost issues and to represent stakeholders' views. The governor shall appoint the members of the advisory council based on the members' 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 must be made by January 1, 2024. 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. **Meetings.** Meetings of the advisory council are subject to chapter 13D. The advisory council shall meet publicly at least every three months to advise the board on drug cost issues related to the prescription drug product information submitted to the board under section 62J.90.

Subd. 6. **Exemption.** Notwithstanding section 15.059, the advisory council shall not expire.

Sec. 11. **[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. Ownership of securities is not a conflict of interest if the securities are: (1) part of a diversified mutual or exchange traded fund; or (2) in a tax-deferred or tax-exempt retirement account that is administered by an independent trustee.

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 must 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. 12. **[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 or more 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 CPI, for:

(A) a 30-day supply lasting a patient for 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 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 to initiate a cost review of a prescription drug product, any member of the board may request a vote to determine whether to review the cost of the prescription drug product.

Sec. 13. **[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 the 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 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 must 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.

(d) The establishment of standards under this subdivision is exempt from the rulemaking requirements under chapter 14, and section 14.386 does not apply.

Sec. 14. **[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 must 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 board shall, and other persons may, notify the Office of the Attorney General of a potential failure by an entity subject to an upper payment limit to comply with that limit.

(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 is not considered noncompliant.

(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. 15. **[62J.93] REPORTS.**

Beginning March 1, 2024, 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. 16. **[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. ERISA plans or Medicare Part D plans 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 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. 17. **[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. 18. Minnesota Statutes 2022, section 151.071, subdivision 1, is amended to read:

Subdivision 1. **Forms of disciplinary action.** When the board finds that a licensee, registrant, or applicant has engaged in conduct prohibited under subdivision 2, it may do one or more of the following:

(1) deny the issuance of a license or registration;

(2) refuse to renew a license or registration;

(3) revoke the license or registration;

(4) suspend the license or registration;

(5) impose limitations, conditions, or both on the license or registration, including but not limited to: the limitation of practice to designated settings; the limitation of the scope of practice within designated settings; the imposition of retraining or rehabilitation requirements; the requirement of practice under supervision; the requirement of participation in a diversion program such as that established pursuant to section 214.31 or the conditioning of continued practice on demonstration of knowledge or skills by appropriate examination or other review of skill and competence;

(6) impose a civil penalty not exceeding $10,000 for each separate violation, except that a civil penalty not exceeding $25,000 may be imposed for each separate violation of section 62J.842, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant of any economic advantage gained by reason of the violation, to discourage similar violations by the licensee or registrant or any other licensee or registrant, or to reimburse the board for the cost of the investigation and proceeding, including but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board members' per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members; and

(7) reprimand the licensee or registrant.

Sec. 19. Minnesota Statutes 2022, section 151.071, subdivision 2, is amended to read:

Subd. 2. **Grounds for disciplinary action.** The following conduct is prohibited and is grounds for disciplinary action:

(1) failure to demonstrate the qualifications or satisfy the requirements for a license or registration contained in this chapter or the rules of the board. The burden of proof is on the applicant to demonstrate such qualifications or satisfaction of such requirements;

(2) obtaining a license by fraud or by misleading the board in any way during the application process or obtaining a license by cheating, or attempting to subvert the licensing examination process. Conduct that subverts or attempts to subvert the licensing examination process includes, but is not limited to: (i) conduct that violates the security of the examination materials, such as removing examination materials from the examination room or having unauthorized possession of any portion of a future, current, or previously administered licensing examination; (ii) conduct that violates the standard of test administration, such as

communicating with another examinee during administration of the examination, copying another examinee's answers, permitting another examinee to copy one's answers, or possessing unauthorized materials; or (iii) impersonating an examinee or permitting an impersonator to take the examination on one's own behalf;

(3) for a pharmacist, pharmacy technician, pharmacist intern, applicant for a pharmacist or pharmacy license, or applicant for a pharmacy technician or pharmacist intern registration, conviction of a felony reasonably related to the practice of pharmacy. Conviction as used in this subdivision includes a conviction of an offense that if committed in this state would be deemed a felony without regard to its designation elsewhere, or a criminal proceeding where a finding or verdict of guilt is made or returned but the adjudication of guilt is either withheld or not entered thereon. The board may delay the issuance of a new license or registration if the applicant has been charged with a felony until the matter has been adjudicated;

(4) for a facility, other than a pharmacy, licensed or registered by the board, if an owner or applicant is convicted of a felony reasonably related to the operation of the facility. The board may delay the issuance of a new license or registration if the owner or applicant has been charged with a felony until the matter has been adjudicated;

(5) for a controlled substance researcher, conviction of a felony reasonably related to controlled substances or to the practice of the researcher's profession. The board may delay the issuance of a registration if the applicant has been charged with a felony until the matter has been adjudicated;

(6) disciplinary action taken by another state or by one of this state's health licensing agencies:

(i) revocation, suspension, restriction, limitation, or other disciplinary action against a license or registration in another state or jurisdiction, failure to report to the board that charges or allegations regarding the person's license or registration have been brought in another state or jurisdiction, or having been refused a license or registration by any other state or jurisdiction. The board may delay the issuance of a new license or registration if an investigation or disciplinary action is pending in another state or jurisdiction until the investigation or action has been dismissed or otherwise resolved; and

(ii) revocation, suspension, restriction, limitation, or other disciplinary action against a license or registration issued by another of this state's health licensing agencies, failure to report to the board that charges regarding the person's license or registration have been brought by another of this state's health licensing agencies, or having been refused a license

or registration by another of this state's health licensing agencies. The board may delay the issuance of a new license or registration if a disciplinary action is pending before another of this state's health licensing agencies until the action has been dismissed or otherwise resolved;

(7) for a pharmacist, pharmacy, pharmacy technician, or pharmacist intern, violation of any order of the board, of any of the provisions of this chapter or any rules of the board or violation of any federal, state, or local law or rule reasonably pertaining to the practice of pharmacy;

(8) for a facility, other than a pharmacy, licensed by the board, violations of any order of the board, of any of the provisions of this chapter or the rules of the board or violation of any federal, state, or local law relating to the operation of the facility;

(9) engaging in any unethical conduct; conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient; or pharmacy practice that is professionally incompetent, in that it may create unnecessary danger to any patient's life, health, or safety, in any of which cases, proof of actual injury need not be established;

(10) aiding or abetting an unlicensed person in the practice of pharmacy, except that it is not a violation of this clause for a pharmacist to supervise a properly registered pharmacy technician or pharmacist intern if that person is performing duties allowed by this chapter or the rules of the board;

(11) for an individual licensed or registered by the board, adjudication as mentally ill or developmentally disabled, or as a chemically dependent person, a person dangerous to the public, a sexually dangerous person, or a person who has a sexual psychopathic personality, by a court of competent jurisdiction, within or without this state. Such adjudication shall automatically suspend a license for the duration thereof unless the board orders otherwise;

(12) for a pharmacist or pharmacy intern, engaging in unprofessional conduct as specified in the board's rules. In the case of a pharmacy technician, engaging in conduct specified in board rules that would be unprofessional if it were engaged in by a pharmacist or pharmacist intern or performing duties specifically reserved for pharmacists under this chapter or the rules of the board;

(13) for a pharmacy, operation of the pharmacy without a pharmacist present and on duty except as allowed by a variance approved by the board;

(14) for a pharmacist, the inability to practice pharmacy with reasonable skill and safety to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills. In the case of registered pharmacy technicians, pharmacist interns, or controlled substance researchers, the inability to carry out duties allowed under this chapter or the rules of the board with reasonable skill and safety to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills;

(15) for a pharmacist, pharmacy, pharmacist intern, pharmacy technician, medical gas dispenser, or controlled substance researcher, revealing a privileged communication from or relating to a patient except when otherwise required or permitted by law;

(16) for a pharmacist or pharmacy, improper management of patient records, including failure to maintain adequate patient records, to comply with a patient's request made pursuant to sections 144.291 to 144.298, or to furnish a patient record or report required by law;

(17) fee splitting, including without limitation:

(i) paying, offering to pay, receiving, or agreeing to receive, a commission, rebate, kickback, or other form of remuneration, directly or indirectly, for the referral of patients;

(ii) referring a patient to any health care provider as defined in sections 144.291 to 144.298 in which the licensee or registrant has a financial or economic interest as defined in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the licensee's or registrant's financial or economic interest in accordance with section 144.6521; and

(iii) any arrangement through which a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved in any manner, directly or indirectly, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefit manager, or other person paying for the prescription or, in the case of veterinary patients, the price for the filled prescription that is charged to the client or other person paying for the prescription, except that a veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified, in writing and with each prescription dispensed, about the arrangement, unless such arrangement involves pharmacy services provided for livestock, poultry, and agricultural production systems, in which case client notification would not be required;

(18) engaging in abusive or fraudulent billing practices, including violations of the federal Medicare and Medicaid laws or state medical assistance laws or rules;

(19) engaging in conduct with a patient that is sexual or may reasonably be interpreted by the patient as sexual, or in any verbal behavior that is seductive or sexually demeaning to a patient;

(20) failure to make reports as required by section 151.072 or to cooperate with an investigation of the board as required by section 151.074;

(21) knowingly providing false or misleading information that is directly related to the care of a patient unless done for an accepted therapeutic purpose such as the dispensing and administration of a placebo;

(22) aiding suicide or aiding attempted suicide in violation of section 609.215 as established by any of the following:

(i) a copy of the record of criminal conviction or plea of guilty for a felony in violation of section 609.215, subdivision 1 or 2;

(ii) a copy of the record of a judgment of contempt of court for violating an injunction issued under section 609.215, subdivision 4;

(iii) a copy of the record of a judgment assessing damages under section 609.215, subdivision 5; or

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board must investigate any complaint of a violation of section 609.215, subdivision 1 or 2;

(23) for a pharmacist, practice of pharmacy under a lapsed or nonrenewed license. For a pharmacist intern, pharmacy technician, or controlled substance researcher, performing duties permitted to such individuals by this chapter or the rules of the board under a lapsed or nonrenewed registration. For a facility required to be licensed under this chapter, operation of the facility under a lapsed or nonrenewed license or registration; ~~and~~

(24) for a pharmacist, pharmacist intern, or pharmacy technician, termination or discharge from the health professionals services program for reasons other than the satisfactory completion of the program~~.~~<u>; and</u>

<u>(25) for a manufacturer, a violation of section 62J.842 or section 62J.845.</u>

Sec. 20. **APPROPRIATION.**

$..... in fiscal year 2024 and $..... in fiscal year 2025 are 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.