State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-SECOND SESSION

H. F. No. 1183

02/18/2021 Authored by Stephenson and Boe
The bill was read for the first time and referred to the Committee on Commerce Finance and Policy
02/25/2021 Adoption of Report: Amended and re-referred to the Committee on Health Finance and Policy

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; imposing civil penalties; amending Minnesota Statutes 2020, 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 is required to maintain a registered agent and office within the state.

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

Subdivision 1. **Notification.** The commissioner of management and budget, the commissioner of human services, any other state agency that provides or purchases a pharmacy benefit, and any entity under contract with a state agency to provide a pharmacy benefit, shall notify the manufacturer of a generic or off-patent drug, the attorney general, and the Board of Pharmacy of any price increase that is in violation of 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 its 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 shall be 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 this section 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 it 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. Minnesota Statutes 2020, 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. 8. Minnesota Statutes 2020, 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>