State of Minnesota

HOUSE OF REPRESENTATIVES

NINETIETH SESSION

H. F. No. 3131

02/26/2018 Authored by Lesch, Omar, Bly, Schultz, Liebling and others
The bill was read for the first time and referred to the Committee on Health and Human Services Reform

A bill for an act

relating to health; prohibiting a manufacturer or wholesale drug distributor from price gouging; allowing the Board of Pharmacy, the commissioner of human services, and health plan companies to notify the attorney general of certain prescription drug price increases; authorizing the attorney general to obtain drug pricing information and take action against drug manufacturers and wholesalers related to certain price increases; imposing civil penalties; amending Minnesota Statutes 2016, sections 8.31, subdivision 1; 151.071, subdivisions 1, 2; proposing coding for new law in Minnesota Statutes, chapter 151.

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

Section 1. Minnesota Statutes 2016, section 8.31, subdivision 1, is amended to read:

Subdivision 1. **Investigate offenses against provisions of certain designated sections; assist in enforcement.** The attorney general shall investigate violations of the law of this state respecting unfair, discriminatory, and other unlawful practices in business, commerce, or trade, and specifically, but not exclusively, prohibition against price gouging for essential off-patent or generic drugs (section 151.462), the Nonprofit Corporation Act (sections 317A.001 to 317A.909), the Act Against Unfair Discrimination and Competition (sections 325D.01 to 325D.07), the Unlawful Trade Practices Act (sections 325D.09 to 325D.16), the Antitrust Act (sections 325D.49 to 325D.66), section 325F.67 and other laws against false or fraudulent advertising, the antidiscrimination acts contained in section 325D.67, the act against monopolization of food products (section 325D.68), the act regulating telephone advertising services (section 325E.39), the Prevention of Consumer Fraud Act (sections 325F.68 to 325F.70), and chapter 53A regulating currency exchanges and assist in the enforcement of those laws as in this section provided.

EFFECTIVE DATE. This section is effective July 1, 2018.

Sec. 2. Minnesota Statutes 2016, 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 $..... may be imposed for each separate violation of section 151.462, 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.

EFFECTIVE DATE. This section is effective July 1, 2018.

Sec. 3. Minnesota Statutes 2016, 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, drunkenness, use of 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, drunkenness, use of 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 distributor, 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; and

(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;

(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 shall 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; and

(25) for a manufacturer or wholesale drug distributor, a violation of section 151.462.

EFFECTIVE DATE. This section is effective July 1, 2018.

Sec. 4. **[151.462] PROHIBITION AGAINST PRICE GOUGING FOR ESSENTIAL OFF-PATENT OR GENERIC DRUGS.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions apply.

(b) "Essential off-patent or generic drug" means any prescription drug:

(1) for which all exclusive marketing rights, if any, granted under the federal Food, Drug, and Cosmetic Act, United States Code, title 21, chapter 9; section 351 of the federal Public Health Service Act, United States Code, title 42, section 262; and federal patent law have expired;

(2) that has been designated by the board or commissioner of human services as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living;

(3) that is actively manufactured and marketed for sale in the United States by three or fewer manufacturers; and

(4) that is made available for sale in the state of Minnesota.

Essential off-patent or generic drug includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights, if any, granted under the federal Food, Drug, and Cosmetic Act, section 351 of the federal Public Health Service Act, and federal patent law have expired.

(c) "Health plan company" has the meaning provided in section 62Q.01, subdivision 4.

(d) "Price gouging" means an unconscionable increase in the price of a prescription drug.

(e) "Unconscionable increase" means an increase in the price of a prescription drug that:

(1) is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and

(2) results in consumers for whom the drug has been prescribed, the commissioner of human services, and health plan companies having no meaningful choice about whether to purchase the drug at an excessive price because of:

(i) the importance of the drug to the health of the consumer; and

(ii) insufficient competition in the market for the drug.

(f) "Wholesale acquisition cost" has the meaning given in United States Code, title 42, section 1395w-3a.

Subd. 2. **Prohibition.** A manufacturer or wholesale drug distributor may not engage in price gouging in the sale of an essential off-patent or generic drug. It is not a violation of this subdivision for a wholesale drug distributor to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale drug distributor by the manufacturer of the drug.

Subd. 3. **Notification of attorney general.** (a) The board, the commissioner of human services, or a health plan company may notify the attorney general of any increase in the price of an essential off-patent or generic drug when:

(1) the price increase, by itself or in combination with other price increases:

(i) would result in an increase of 50 percent or more, compared to the preceding one-year period, in the wholesale acquisition cost of the drug or other relevant measure of drug cost; or

(ii) would result in an increase of 50 percent or more in the price paid by the medical assistance or MinnesotaCare programs, or the health plan company, for the drug compared to the preceding one-year period; and

(2)(i) a 30-day supply of the maximum recommended dosage of the drug for any indication, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost;

(ii) a full course of treatment with the drug, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost; or

(iii) if the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment, or a single dose, it would cost more than $80 at the drug's wholesale acquisition cost to obtain a 30-day supply or a full course of treatment.

The commissioner of human services and the health plan company shall notify the board of any notification to the attorney general provided under this paragraph.

(b) On request of the attorney general, the manufacturer of an essential off-patent or generic drug identified in a notice under paragraph (a) shall, within 45 days after the request, submit a statement to the attorney general:

(1) itemizing the components of the cost of producing the drug;

(2) identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug within the one-year period preceding the date of the price increase;

(3) identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug and explaining any improvement in public health associated with those expenditures; and

(4) providing any other information that the manufacturer believes to be relevant to a determination of whether a violation of this section has occurred.

(c) The attorney general may require a manufacturer or a wholesale drug distributor to produce any records or other documents that may be relevant to a determination of whether a violation of this section has occurred. The attorney general or a person may use the powers and procedures provided in this section or section 8.31.

(d) The attorney general may not bring an action for a remedy under paragraph (c) unless the attorney general has provided the manufacturer or wholesale drug distributor an opportunity to meet with the attorney general to offer a justification for the increase in the price of the essential off-patent or generic drug.

(e) The attorney general shall make any information provided by a health plan company, manufacturer, or wholesale drug distributor under paragraphs (a), (b), and (c) available to the board upon request. Any information provided by a health plan company, manufacturer, or wholesale drug distributor to the attorney general under paragraphs (a), (b), and (c) shall be treated as nonpublic data under section 13.02, subdivision 9, unless the nonpublic classification of the information is waived by the health plan company, manufacturer, or wholesale drug distributor.

(f) In any action brought by the attorney general under paragraph (c), a person who is alleged to have violated a requirement of this section may not assert as a defense that the person did not deal directly with a consumer residing in the state.

Subd. 4. **Private right of action.** In addition to remedies otherwise provided by law, any person injured by a violation of this section may bring a civil action and recover damages, together with costs and disbursements, including costs of investigation and reasonable attorney fees, and receive other equitable relief as determined by the court. The court may, as appropriate, enter a consent judgment or decree without the finding of illegality. Any civil action brought under this subdivision is for the benefit of the public.

EFFECTIVE DATE. This section is effective July 1, 2018.