

SENATE
STATE OF MINNESOTA
NINETY-SECOND SESSION

S.F. No. 1265

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DATE	D-PG	OFFICIAL STATUS
02/22/2021	482	Introduction and first reading
		Referred to Health and Human Services Finance and Policy
03/01/2021	627	Author added Hoffman

1.1 A bill for an act

1.2 relating to health; prohibiting a manufacturer or wholesale drug distributor from

1.3 charging unconscionable prices for prescription drugs; requiring the Board of

1.4 Pharmacy, the commissioner of human services, and health plan companies to

1.5 notify the attorney general of certain prescription drug price increases; authorizing

1.6 the attorney general to take action against drug manufacturers and wholesalers

1.7 related to certain price increases; imposing civil penalties; appropriating money;

1.8 amending Minnesota Statutes 2020, sections 8.31, subdivision 1; 151.071,

1.9 subdivisions 1, 2; proposing coding for new law in Minnesota Statutes, chapter

1.10 151.

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

1.12 Section 1. Minnesota Statutes 2020, section 8.31, subdivision 1, is amended to read:

1.13 Subdivision 1. **Investigate offenses against provisions of certain designated sections;**

1.14 **assist in enforcement.** The attorney general shall investigate violations of the law of this

1.15 state respecting unfair, discriminatory, and other unlawful practices in business, commerce,

1.16 or trade, and specifically, but not exclusively, the Prohibition Against Charging

1.17 Unconscionable Prices for Prescription Drugs (section 151.462), the Nonprofit Corporation

1.18 Act (sections 317A.001 to 317A.909), the Act Against Unfair Discrimination and

1.19 Competition (sections 325D.01 to 325D.07), the Unlawful Trade Practices Act (sections

1.20 325D.09 to 325D.16), the Antitrust Act (sections 325D.49 to 325D.66), section 325F.67

1.21 and other laws against false or fraudulent advertising, the antidiscrimination acts contained

1.22 in section 325D.67, the act against monopolization of food products (section 325D.68), the

1.23 act regulating telephone advertising services (section 325E.39), the Prevention of Consumer

1.24 Fraud Act (sections 325F.68 to 325F.70), and chapter 53A regulating currency exchanges

1.25 and assist in the enforcement of those laws as in this section provided.

2.1 Sec. 2. Minnesota Statutes 2020, section 151.071, subdivision 1, is amended to read:

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

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

2.6 (2) refuse to renew a license or registration;

2.7 (3) revoke the license or registration;

2.8 (4) suspend the license or registration;

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

2.16 (6) impose a civil penalty not exceeding \$10,000 for each separate violation, except that
2.17 a civil penalty not exceeding \$25,000 may be imposed for each separate violation of section
2.18 151.462, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant
2.19 of any economic advantage gained by reason of the violation, to discourage similar violations
2.20 by the licensee or registrant or any other licensee or registrant, or to reimburse the board
2.21 for the cost of the investigation and proceeding, including but not limited to, fees paid for
2.22 services provided by the Office of Administrative Hearings, legal and investigative services
2.23 provided by the Office of the Attorney General, court reporters, witnesses, reproduction of
2.24 records, board members' per diem compensation, board staff time, and travel costs and
2.25 expenses incurred by board staff and board members; and

2.26 (7) reprimand the licensee or registrant.

2.27 Sec. 3. Minnesota Statutes 2020, section 151.071, subdivision 2, is amended to read:

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

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

3.1 (2) obtaining a license by fraud or by misleading the board in any way during the
3.2 application process or obtaining a license by cheating, or attempting to subvert the licensing
3.3 examination process. Conduct that subverts or attempts to subvert the licensing examination
3.4 process includes, but is not limited to: (i) conduct that violates the security of the examination
3.5 materials, such as removing examination materials from the examination room or having
3.6 unauthorized possession of any portion of a future, current, or previously administered
3.7 licensing examination; (ii) conduct that violates the standard of test administration, such as
3.8 communicating with another examinee during administration of the examination, copying
3.9 another examinee's answers, permitting another examinee to copy one's answers, or
3.10 possessing unauthorized materials; or (iii) impersonating an examinee or permitting an
3.11 impersonator to take the examination on one's own behalf;

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

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

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

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

3.31 (i) revocation, suspension, restriction, limitation, or other disciplinary action against a
3.32 license or registration in another state or jurisdiction, failure to report to the board that
3.33 charges or allegations regarding the person's license or registration have been brought in
3.34 another state or jurisdiction, or having been refused a license or registration by any other

4.1 state or jurisdiction. The board may delay the issuance of a new license or registration if an
4.2 investigation or disciplinary action is pending in another state or jurisdiction until the
4.3 investigation or action has been dismissed or otherwise resolved; and

4.4 (ii) revocation, suspension, restriction, limitation, or other disciplinary action against a
4.5 license or registration issued by another of this state's health licensing agencies, failure to
4.6 report to the board that charges regarding the person's license or registration have been
4.7 brought by another of this state's health licensing agencies, or having been refused a license
4.8 or registration by another of this state's health licensing agencies. The board may delay the
4.9 issuance of a new license or registration if a disciplinary action is pending before another
4.10 of this state's health licensing agencies until the action has been dismissed or otherwise
4.11 resolved;

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

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

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

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

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

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

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

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

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

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

5.23 (17) fee splitting, including without limitation:

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

5.26 (ii) referring a patient to any health care provider as defined in sections 144.291 to
5.27 144.298 in which the licensee or registrant has a financial or economic interest as defined
5.28 in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the
5.29 licensee's or registrant's financial or economic interest in accordance with section 144.6521;
5.30 and

5.31 (iii) any arrangement through which a pharmacy, in which the prescribing practitioner
5.32 does not have a significant ownership interest, fills a prescription drug order and the
5.33 prescribing practitioner is involved in any manner, directly or indirectly, in setting the price

6.1 for the filled prescription that is charged to the patient, the patient's insurer or pharmacy
6.2 benefit manager, or other person paying for the prescription or, in the case of veterinary
6.3 patients, the price for the filled prescription that is charged to the client or other person
6.4 paying for the prescription, except that a veterinarian and a pharmacy may enter into such
6.5 an arrangement provided that the client or other person paying for the prescription is notified,
6.6 in writing and with each prescription dispensed, about the arrangement, unless such
6.7 arrangement involves pharmacy services provided for livestock, poultry, and agricultural
6.8 production systems, in which case client notification would not be required;

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

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

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

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

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

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

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

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

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

6.30 (23) for a pharmacist, practice of pharmacy under a lapsed or nonrenewed license. For
6.31 a pharmacist intern, pharmacy technician, or controlled substance researcher, performing
6.32 duties permitted to such individuals by this chapter or the rules of the board under a lapsed

7.1 or nonrenewed registration. For a facility required to be licensed under this chapter, operation
 7.2 of the facility under a lapsed or nonrenewed license or registration; ~~and~~

7.3 (24) for a pharmacist, pharmacist intern, or pharmacy technician, termination or discharge
 7.4 from the health professionals services program for reasons other than the satisfactory
 7.5 completion of the program; and

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

7.7 **Sec. 4. [151.462] PROHIBITION AGAINST CHARGING UNCONSCIONABLE**
 7.8 **PRICES FOR PRESCRIPTION DRUGS.**

7.9 Subdivision 1. **Purpose.** The purpose of this section is to promote public health in
 7.10 Minnesota by preventing unconscionable price gouging with respect to the price of essential
 7.11 prescription drugs sold in Minnesota. Essential prescription drugs are a necessity. These
 7.12 drugs, which are made available in this state by drug manufacturers and wholesale
 7.13 distributors, provide critically important benefits to the health and well-being of Minnesota
 7.14 citizens. Abuses in the pricing of various essential prescription drugs are well-documented,
 7.15 jeopardize the health and welfare of the public, and have caused the death of patients who
 7.16 could not afford to pay an unconscionable price for these drugs. For example, these price
 7.17 gouging practices have created a public health catastrophe in Minnesota regarding the sale
 7.18 of insulin, an essential prescription drug for the treatment of more than 320,000 people
 7.19 residing in Minnesota who are diabetic. This section is intended to address such abuses, but
 7.20 allow drug manufacturers and wholesale drug distributors a fair rate of return with respect
 7.21 to their sale of essential prescription drugs in the state of Minnesota.

7.22 Subd. 2. **Definitions.** (a) For purposes of this section, the following definitions apply.

7.23 (b) "Essential prescription drug" means a patented (including an exclusivity-protected
 7.24 drug), off-patent, or generic drug prescribed in Minnesota by a practitioner:

7.25 (1) that either:

7.26 (i) is covered under the medical assistance program or by any Medicare Part D plan
 7.27 offered in the state of Minnesota; or

7.28 (ii) has been designated by the commissioner of human services under subdivision 4 as
 7.29 an essential medicine due to its efficacy in treating a life-threatening health condition or a
 7.30 chronic health condition that substantially impairs an individual's ability to engage in
 7.31 activities of daily living; and

7.32 (2) for which:

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

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

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

8.10 Essential prescription drug also includes a patented or off-patent drug-device combination
8.11 product, whose wholesale acquisition cost is more than \$80, and which is used at least in
8.12 part for delivery of a drug described in this paragraph.

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

8.14 (d) "Unconscionable price" means a price that:

8.15 (1) is not reasonably justified by the actual cost of inventing, producing, selling, and
8.16 distributing the essential prescription drug, and any actual cost of an appropriate expansion
8.17 of access to the drug to promote public health; and

8.18 (2) applies to an essential prescription drug sold to:

8.19 (i) consumers in Minnesota;

8.20 (ii) the commissioner of human services for use in a Minnesota public health care
8.21 program; or

8.22 (iii) a health plan company providing medical care to Minnesota consumers; and the
8.23 consumer, commissioner, or health plan company has no meaningful choice about whether
8.24 to purchase the drug, because there is no other comparable drug sold in Minnesota at a price
8.25 that is reasonably justified by the actual cost of inventing, producing, selling, and distributing
8.26 the comparable drug, and any actual cost of an appropriate expansion of access to the drug
8.27 to promote public health.

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

8.30 Subd. 3. **Prohibition.** No drug manufacturer or wholesale drug distributor shall charge
8.31 or cause to be charged in Minnesota an unconscionable price for an essential prescription
8.32 drug sold in Minnesota. It is not a violation of this section for a wholesale drug distributor

9.1 to charge a price for an essential prescription drug to be sold in Minnesota that is directly
9.2 and substantially attributable to the cost of the drug charged by the manufacturer.

9.3 Subd. 4. **Commissioner of human services; list of essential prescription drugs.** The
9.4 commissioner of human services, in consultation with the Formulary Committee established
9.5 under section 256B.0625, subdivision 13c, may designate essential medicines in accordance
9.6 with subdivision 2, paragraph (b), clause (1), item (ii), and shall maintain a list of all essential
9.7 prescription drugs on the agency website. The commissioner is exempt from the rulemaking
9.8 requirements of chapter 14 in making the essential medicine designation and compiling the
9.9 list of all essential prescription drugs under this subdivision.

9.10 Subd. 5. **Notification of attorney general.** The Minnesota Board of Pharmacy, the
9.11 commissioner of human services, and health plan companies shall notify the attorney general
9.12 of any increase of 15 percent or more during a one-year period in the price of any essential
9.13 prescription drug sold in Minnesota.

9.14 Subd. 6. **Attorney general's office to confer with drug manufacturer or distributor.** In
9.15 order for the attorney general to bring an action for an alleged violation of subdivision 3
9.16 against a drug manufacturer or wholesale distributor, the attorney general must have provided
9.17 the manufacturer or wholesale distributor an opportunity to meet with the attorney general
9.18 to present any justification for the price of the essential prescription drug. This meeting
9.19 shall be in addition to any response or responses that the drug manufacturer or wholesale
9.20 distributor may make to prelitigation investigation or discovery conducted by the attorney
9.21 general pursuant to section 8.31.

9.22 Subd. 7. **Private right of action.** Any action brought pursuant to section 8.31, subdivision
9.23 3a, by a person injured by a violation of this section is for the benefit of the public.

9.24 Subd. 8. **Severability.** In accordance with section 645.20, it is the intent of the legislature
9.25 that the provisions, or any part of a provision, of this section or its effective date are severable
9.26 in the event any provision, or any part of a provision, of this section or its effective date is
9.27 found by a court to be unconstitutional.

9.28 **EFFECTIVE DATE.** This section is effective the day following final enactment and,
9.29 notwithstanding any statutory or common law to the contrary, applies retroactively to any
9.30 prices charged by a drug manufacturer or drug wholesaler for essential prescription drugs
9.31 sold or distributed in Minnesota on or after July 1, 2015.

10.1 Sec. 5. **APPROPRIATION.**

10.2 (a) \$46,000 in fiscal year 2022 is appropriated from the general fund to the commissioner
10.3 of human services to implement Minnesota Statutes, section 151.462. The base for this
10.4 appropriation is \$52,000 in fiscal year 2023 and \$52,000 in fiscal year 2024. There is federal
10.5 financial participation of \$15,000 in fiscal year 2022 and \$17,000 per year thereafter.

10.6 (b) \$427,000 in fiscal year 2022 is appropriated from the general fund to the attorney
10.7 general to enforce Minnesota Statutes, section 151.462. The base for this appropriation is
10.8 \$527,000 in fiscal year 2023 and \$527,000 in fiscal year 2024.