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State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-THIRD SESSION

H. F. No. 4991

03/18/2024 Authored by Lislegard, Rehm, Skraba and Zeleznikar The bill was read for the first time and referred to the Committee on Commerce Finance and Policy

1.1 A bill for an act
1.2 relating to health; prohibiting manufacturers and wholesale distributors from
1.3 limiting pharmacy access to 340B drugs; amending Minnesota Statutes 2023
1.4 Supplement, section 151.071, subdivision 2; proposing coding for new law in
1.5 Minnesota Statutes, chapter 62J.

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

1.7 Section 1. 62J.96 ACCESS TO 340B DRUGS.

1.8 Subdivision 1. Manufacturers and distributors. A manufacturer or wholesale drug
1.9 distributor shall not restrict, prohibit, or otherwise interfere with, directly or indirectly, the
1.10 delivery or distribution of a 340B drug, to a pharmacy that is under contract with a 340B
1.11 covered entity to receive and dispense 340B drugs on behalf of the covered entity, unless
1.12 the delivery or distribution of the drug to the pharmacy is prohibited under the 340B Drug
1.13 Pricing Program.

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

1.15 (b) "Manufacturer" has the meaning provided in section 151.01, subdivision 14a.

1.16 (c) "340B covered entity" has the meaning provided in section 340B(a)(4) of the Public
1.17 Health Service Act.

1.18 (d) "Wholesale distributor" means an entity required to be licensed under section 151.47.

1.19 Sec. 2. Minnesota Statutes 2023 Supplement, section 151.071, subdivision 2, is amended
1.20 to read:

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

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

2.4 (2) obtaining a license by fraud or by misleading the board in any way during the
2.5 application process or obtaining a license by cheating, or attempting to subvert the licensing
2.6 examination process. Conduct that subverts or attempts to subvert the licensing examination
2.7 process includes, but is not limited to: (i) conduct that violates the security of the examination
2.8 materials, such as removing examination materials from the examination room or having
2.9 unauthorized possession of any portion of a future, current, or previously administered
2.10 licensing examination; (ii) conduct that violates the standard of test administration, such as
2.11 communicating with another examinee during administration of the examination, copying
2.12 another examinee's answers, permitting another examinee to copy one's answers, or
2.13 possessing unauthorized materials; or (iii) impersonating an examinee or permitting an
2.14 impersonator to take the examination on one's own behalf;

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

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

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

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

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

3.8 (ii) revocation, suspension, restriction, limitation, or other disciplinary action against a
3.9 license or registration issued by another of this state's health licensing agencies, failure to
3.10 report to the board that charges regarding the person's license or registration have been
3.11 brought by another of this state's health licensing agencies, or having been refused a license
3.12 or registration by another of this state's health licensing agencies. The board may delay the
3.13 issuance of a new license or registration if a disciplinary action is pending before another
3.14 of this state's health licensing agencies until the action has been dismissed or otherwise
3.15 resolved;

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

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

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

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

3.32 (11) for an individual licensed or registered by the board, adjudication as mentally ill
3.33 or developmentally disabled, or as a chemically dependent person, a person dangerous to
3.34 the public, a sexually dangerous person, or a person who has a sexual psychopathic

4.1 personality, by a court of competent jurisdiction, within or without this state. Such
4.2 adjudication shall automatically suspend a license for the duration thereof unless the board
4.3 orders otherwise;

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

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

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

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

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

4.26 (17) fee splitting, including without limitation:

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

4.29 (ii) referring a patient to any health care provider as defined in sections 144.291 to
4.30 144.298 in which the licensee or registrant has a financial or economic interest as defined
4.31 in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the
4.32 licensee's or registrant's financial or economic interest in accordance with section 144.6521;
4.33 and

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

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

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

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

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

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

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

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

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

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

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

6.6 (24) for a pharmacist, pharmacist intern, or pharmacy technician, termination or discharge
6.7 from the health professionals services program for reasons other than the satisfactory
6.8 completion of the program; ~~and~~

6.9 (25) for a manufacturer, a violation of section 62J.842 or 62J.845; and

6.10 (26) for a manufacturer or wholesale distributor, a violation of section 62J.96.