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State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. **3805**

02/26/2020 Authored by Elkins, Baker, Moran, Hamilton, Liebling and others
The bill was read for the first time and referred to the Committee on Commerce

1.1 A bill for an act
1.2 relating to health insurance; requiring manufacturers to report prescription drug
1.3 prices and maintain prices; amending Minnesota Statutes 2018, section 62A.02,
1.4 subdivision 1; Minnesota Statutes 2019 Supplement, section 151.071, subdivision
1.5 2; proposing coding for new law in Minnesota Statutes, chapter 151.

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

1.7 Section 1. Minnesota Statutes 2018, section 62A.02, subdivision 1, is amended to read:

1.8 Subdivision 1. **Filing.** For purposes of this section, "health plan" means a health plan
1.9 as defined in section 62A.011 or a policy of accident and sickness insurance as defined in
1.10 section 62A.01. No health plan shall be issued or delivered to any person in this state, nor
1.11 shall any application, rider, or endorsement be used in connection with the health plan, until
1.12 a copy of its form and of the classification of risks and the premium rates pertaining to the
1.13 form have been filed with the commissioner. The filing must include the health plan's
1.14 prescription drug formulary. The filing for nongroup health plan forms shall include a
1.15 statement of actuarial reasons and data to support the rate. For health benefit plans as defined
1.16 in section 62L.02, and for health plans to be issued to individuals, the health carrier shall
1.17 file with the commissioner the information required in section 62L.08, subdivision 8. For
1.18 group health plans for which approval is sought for sales only outside of the small employer
1.19 market as defined in section 62L.02, this section applies only to policies or contracts of
1.20 accident and sickness insurance. All forms intended for issuance in the individual or small
1.21 employer market must be accompanied by a statement as to the expected loss ratio for the
1.22 form. Premium rates and forms relating to specific insureds or proposed insureds, whether
1.23 individuals or groups, need not be filed, unless requested by the commissioner.

2.1 Sec. 2. Minnesota Statutes 2019 Supplement, section 151.071, subdivision 2, is amended
2.2 to read:

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

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

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

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

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

2.32 (5) for a controlled substance researcher, conviction of a felony reasonably related to
2.33 controlled substances or to the practice of the researcher's profession. The board may delay

3.1 the issuance of a registration if the applicant has been charged with a felony until the matter
3.2 has been adjudicated;

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

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

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

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

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

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

3.32 (10) aiding or abetting an unlicensed person in the practice of pharmacy, except that it
3.33 is not a violation of this clause for a pharmacist to supervise a properly registered pharmacy

4.1 technician or pharmacist intern if that person is performing duties allowed by this chapter
4.2 or the rules of the board;

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

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

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

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

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

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

4.31 (17) fee splitting, including without limitation:

4.32 (i) paying, offering to pay, receiving, or agreeing to receive, a commission, rebate,
4.33 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 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 drug manufacturer, failure to comply with section 151.80.

Sec. 3. **[151.80] REPORTING PRESCRIPTION DRUG PRICES.**

Subdivision 1. Definitions. (a) For purposes of this section, the terms in this subdivision have the meanings given them.

(b) "Anatomical therapeutic chemical code" means the code given to a drug by the World Health Organization classification system that groups the drug's active medical substances according to the organ or system on which the drug acts and the drug's therapeutic, pharmacological, and chemical properties.

(c) "Average wholesale price" means the customary reference price for sales by a drug wholesaler to a retail pharmacy, as established and published by the manufacturer.

(d) "Brand name drug" means a drug, including therapeutic biological products, marketed under a proprietary, trademark-protected name.

(e) "Commissioner" means the commissioner of commerce.

(f) "Generic drug" means a drug created to be identical to an existing brand name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.

(g) "Generic product identifier" means a 14-character code that defines pharmaceutically equivalent drugs that are identical in terms of active ingredient, route of administration, dosage form, strength or concentration, and therapeutic use.

7.1 (h) "National drug code" means the numerical code maintained by the United States
7.2 Food and Drug Administration, and includes the label code, product code, and package
7.3 code.

7.4 (i) "Wholesale acquisition cost" has the meaning given in United States Code, title 42,
7.5 section 1395w-3a(c)(6)(B).

7.6 (j) "Unit" has the meaning given in United States Code, title 42, section 1395w-3a(b)(2).

7.7 Subd. 2. **Price reporting.** (a) Beginning January 30, 2021, and by January 30 each year
7.8 thereafter, a manufacturer must report to the commissioner the information in paragraph
7.9 (b) for every drug with a wholesale acquisition cost of \$25 or more, as applicable to the
7.10 next calendar year.

7.11 (b) A manufacturer shall report a drug's:

7.12 (1) national drug code, labeler code, and the manufacturer name associated with the
7.13 labeler code;

7.14 (2) brand name, if applicable;

7.15 (3) generic name, if applicable;

7.16 (4) generic product identifier and associated description;

7.17 (5) anatomical therapeutic chemical code and associated description;

7.18 (6) wholesale acquisition cost for one unit;

7.19 (7) measure that constitutes a wholesale acquisition cost unit;

7.20 (8) average wholesale price; and

7.21 (9) status as brand name or generic.

7.22 (c) The effective date of the information described in paragraph (b) must be included in
7.23 the report to the commissioner.

7.24 (d) A manufacturer must report the information described in this subdivision in the form
7.25 and manner specified by the commissioner.

7.26 (e) Information reported under this subdivision is classified as public data not on
7.27 individuals, as defined in section 13.02, subdivision 14, and must not be classified by the
7.28 manufacturer as trade secret information, as defined in section 13.37, subdivision 1, paragraph
7.29 (b).

8.1 (f) A manufacturer's failure to report the information required by this subdivision is
8.2 grounds for disciplinary action under section 151.071.

8.3 Subd. 3. **Public posting of prescription drug price information.** By April 1 each year,
8.4 the commissioner must post to the department's website, in an easy-to-read format, the
8.5 information provided under subdivision 2.

8.6 Subd. 4. **Price change.** (a) If a drug is included in the formulary of a health plan submitted
8.7 to and approved by the commissioner of commerce for the next calendar year under section
8.8 62A.02, subdivision 1, the manufacturer must not increase the wholesale acquisition cost
8.9 of a drug for the next calendar year.

8.10 (b) A manufacturer's failure to meet the requirements of paragraph (a) is grounds for
8.11 disciplinary action under section 151.071.