

A bill for an act

relating to health; requiring the Board of Pharmacy to adopt rules regarding the substitution of drugs to treat epilepsy or seizures if the United States Food and Drug Administration determines that substitution may cause a health risk to patients; amending Minnesota Statutes 2008, section 151.06, subdivision 1.

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

Section 1. Minnesota Statutes 2008, section 151.06, subdivision 1, is amended to read:

Subdivision 1. **Generally; rules.** (a) Powers and duties. The Board of Pharmacy shall have the power and it shall be its duty:

(1) to regulate the practice of pharmacy;

(2) to regulate the manufacture, wholesale, and retail sale of drugs within this state;

(3) to regulate the identity, labeling, purity, and quality of all drugs and medicines dispensed in this state, using the United States Pharmacopeia and the National Formulary, or any revisions thereof, or standards adopted under the federal act as the standard;

(4) to enter and inspect by its authorized representative any and all places where drugs, medicines, medical gases, or veterinary drugs or devices are sold, vended, given away, compounded, dispensed, manufactured, wholesaled, or held; it may secure samples or specimens of any drugs, medicines, medical gases, or veterinary drugs or devices after paying or offering to pay for such sample; it shall be entitled to inspect and make copies of any and all records of shipment, purchase, manufacture, quality control, and sale of these items provided, however, that such inspection shall not extend to financial data, sales data, or pricing data;

(5) to examine and license as pharmacists all applicants whom it shall deem qualified to be such;

(6) to license wholesale drug distributors;

(7) to deny, suspend, revoke, or refuse to renew any registration or license required under this chapter, to any applicant or registrant or licensee upon any of the following grounds:

(i) fraud or deception in connection with the securing of such license or registration;

(ii) in the case of a pharmacist, conviction in any court of a felony;

(iii) in the case of a pharmacist, conviction in any court of an offense involving moral turpitude;

(iv) habitual indulgence in the use of narcotics, stimulants, or depressant drugs; or habitual indulgence in intoxicating liquors in a manner which could cause conduct endangering public health;

(v) unprofessional conduct or conduct endangering public health;

(vi) gross immorality;

(vii) employing, assisting, or enabling in any manner an unlicensed person to practice pharmacy;

(viii) conviction of theft of drugs, or the unauthorized use, possession, or sale thereof;

(ix) violation of any of the provisions of this chapter or any of the rules of the State Board of Pharmacy;

(x) in the case of a pharmacy license, operation of such pharmacy without a pharmacist present and on duty;

(xi) in the case of a pharmacist, physical or mental disability which could cause incompetency in the practice of pharmacy;

(xii) in the case of a pharmacist, the suspension or revocation of a license to practice pharmacy in another state; or

(xiii) in the case of a pharmacist, aiding suicide or aiding attempted suicide in violation of section 609.215 as established by any of the following:

(A) 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;

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

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

(D) 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;

(8) to employ necessary assistants and adopt rules for the conduct of its business;

3.1 (9) to register as pharmacy technicians all applicants who the board determines are
3.2 qualified to carry out the duties of a pharmacy technician; and

3.3 (10) to perform such other duties and exercise such other powers as the provisions of
3.4 the act may require.

3.5 (b) Temporary suspension. In addition to any other remedy provided by law, the
3.6 board may, without a hearing, temporarily suspend a license for not more than 60 days if
3.7 the board finds that a pharmacist has violated a statute or rule that the board is empowered
3.8 to enforce and continued practice by the pharmacist would create an imminent risk of
3.9 harm to others. The suspension shall take effect upon written notice to the pharmacist,
3.10 specifying the statute or rule violated. At the time it issues the suspension notice, the
3.11 board shall schedule a disciplinary hearing to be held under the Administrative Procedure
3.12 Act. The pharmacist shall be provided with at least 20 days' notice of any hearing held
3.13 under this subdivision.

3.14 (c) Rules. For the purposes aforesaid, it shall be the duty of the board to make
3.15 and publish uniform rules not inconsistent herewith for carrying out and enforcing
3.16 the provisions of this chapter. The board shall adopt rules regarding prospective drug
3.17 utilization review and patient counseling by pharmacists. A pharmacist in the exercise of
3.18 the pharmacist's professional judgment, upon the presentation of a new prescription by a
3.19 patient or the patient's caregiver or agent, shall perform the prospective drug utilization
3.20 review required by rules issued under this subdivision.

3.21 (d) Substitution; rules. If the United States Food and Drug Administration
3.22 (FDA) determines that the substitution of drugs used for the treatment of epilepsy or
3.23 seizures poses a health risk to patients, the board shall adopt rules in accordance with
3.24 accompanying FDA interchangeability standards regarding the use of substitution for
3.25 these drugs. If the board adopts a rule regarding the substitution of drugs used for the
3.26 treatment of epilepsy or seizures that conflicts with the substitution requirements of
3.27 section 151.21, subdivision 3, the rule shall supersede the conflicting statute. If the rule
3.28 proposed by the board would increase state costs for state public health care programs,
3.29 the board shall report to the chairs and ranking minority members of the senate Health
3.30 and Human Services Budget Division and the house of representatives Health Care and
3.31 Human Services Finance Division the proposed rule and the increased cost associated
3.32 with the proposed rule before the board may adopt the rule.