CHAPTER 151

PHARMACY

151.01 DEFINITIONS.

[For text of subds 1 to 30, see M.S.2006]

Subd. 31. **Central service pharmacy.** "Central service pharmacy" means a pharmacy that may provide dispensing functions, drug utilization review, packaging, labeling, or delivery of a prescription product to another pharmacy for the purpose of filling a prescription.

Subd. 32. **Electronic signature.** "Electronic signature" means an electronic sound, symbol, or process attached to or associated with a record and executed or adopted by a person with the intent to sign the record.

Subd. 33. **Electronic transmission.** "Electronic transmission" means transmission of information in electronic form.

History: *2007 c 103 s 1; 2007 c 123 s 122,123*

151.06 POWERS AND DUTIES.

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;

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

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

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

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

[For text of subds 1a to 5, see M.S.2006]

History: *2007 c 123 s 124*

151.19 REGISTRATION; FEES.

[For text of subd 1, see M.S.2006]

Subd. 2. **Nonresident pharmacies.** The board shall require and provide for an annual nonresident special pharmacy registration for all pharmacies located outside of this state that

regularly dispense medications for Minnesota residents and mail, ship, or deliver prescription medications into this state. Nonresident special pharmacy registration shall be granted by the board upon the disclosure and certification by a pharmacy:

(1) that it is licensed in the state in which the dispensing facility is located and from which the drugs are dispensed;

(2) the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing drugs to residents of this state;

(3) that it complies with all lawful directions and requests for information from the Board of Pharmacy of all states in which it is licensed or registered, except that it shall respond directly to all communications from the board concerning emergency circumstances arising from the dispensing of drugs to residents of this state;

(4) that it maintains its records of drugs dispensed to residents of this state so that the records are readily retrievable from the records of other drugs dispensed;

(5) that it cooperates with the board in providing information to the Board of Pharmacy of the state in which it is licensed concerning matters related to the dispensing of drugs to residents of this state;

(6) that during its regular hours of operation, but not less than six days per week, for a minimum of 40 hours per week, a toll–free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patients' records; the toll–free number must be disclosed on the label affixed to each container of drugs dispensed to residents of this state; and

(7) that, upon request of a resident of a long–term care facility located within the state of Minnesota, the resident's authorized representative, or a contract pharmacy or licensed health care facility acting on behalf of the resident, the pharmacy will dispense medications prescribed for the resident in unit–dose packaging or, alternatively, comply with the provisions of section 151.415, subdivision 5.

[For text of subd 3, see M.S.2006]

History: *2007 c 147 art 11 s 4*

151.21 SUBSTITUTION.

Subdivision 1. **Generally.** Except as provided in this section, it shall be unlawful for any pharmacist or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber.

Subd. 2. **Brand name specified.** When a pharmacist receives a paper or hard copy prescription on which the prescriber has personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has expressly indicated that the prescription is to be dispensed as communicated, the pharmacist shall dispense the brand name legend drug as prescribed.

Subd. 3. **Brand name not specified.** When a pharmacist receives a paper or hard copy prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has not expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the substitu-

tion to the purchaser, dispense the generic drug, unless the purchaser objects. A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug product unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug other than the brand name drug prescribed.

Subd. 3a. **Prescriptions by electronic transmission.** Nothing in this section permits a prescriber to maintain "dispense as written" or "D.A.W." as a default on all prescriptions. Prescribers must add the "dispense as written" or "D.A.W." designation to electronic prescriptions individually, as appropriate.

[For text of subds 4 to 8, see M.S.2006]

History: *2007 c 123 s 125–128*

151.215 CERTIFICATION.

A pharmacist must certify a prescription, in compliance with Minnesota Board of Pharmacy rules, before the prescription is dispensed, delivered, mailed, or shipped to a patient or a patient's caregiver. However, if the prescription has been certified by a pharmacist at a licensed central service pharmacy, in compliance with Minnesota Board of Pharmacy rules, an additional certification is not required at the pharmacy that dispenses, mails, or ships the completed prescription to the patient.

History: *2007 c 103 s 2*

151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.

[For text of subd 1, see M.S.2006]

Subd. 2. **Prescribing and filing.** (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner's direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9, physician assistant, or medical student or resident to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18.

(b) A licensed practitioner that dispenses for profit a legend drug that is to be administered orally, is ordinarily dispensed by a pharmacist, and is not a vaccine, must file with the practitioner's licensing board a statement indicating that the practitioner dispenses legend drugs for profit, the general circumstances under which the practitioner dispenses for profit, and the types of legend drugs generally dispensed. It is unlawful to dispense legend drugs for profit after July 31, 1990, unless the statement has been filed with the appropriate licensing board. For purposes of this paragraph, "profit" means (1) any amount received by the practitioner in excess of the acquisition cost of a legend drug for legend drugs that are purchased in prepackaged form, or (2) any amount received by the practitioner in excess of the acquisition cost of a legend drug plus the cost of making the drug available if the legend drug requires compounding, packaging, or other treatment. The statement filed under this paragraph is public data under section 13.03. This paragraph does not apply to a licensed doctor of veterinary medicine or a registered pharmacist. Any person other than a licensed practitioner with

the authority to prescribe, dispense, and administer a legend drug under paragraph (a) shall not dispense for profit. To dispense for profit does not include dispensing by a community health clinic when the profit from dispensing is used to meet operating expenses.

(c) A prescription or drug order for a legend drug is not valid if it is based solely on an online questionnaire, unless it can be established that the prescription or order was based on a documented patient evaluation adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment.

[For text of subds 2a to 11, see M.S.2006]

History: *2007 c 103 s 3; 2007 c 147 art 12 s 7*

151.415 LONG–TERM CARE RESIDENT ACCESS TO PHARMACEUTICALS ACT.

Subdivision 1. **Title; citation.** This section may be cited as the "Long–Term Care Resident Access to Pharmaceuticals Act."

Subd. 2. **Definitions.** For the purposes of this section, the following terms have the meanings given them unless otherwise provided by text:

(a) "Board" means the Board of Pharmacy.

(b) "Contract pharmacy" means a pharmacy, licensed under this chapter, which is under contract to a long–term care facility.

(c) "Long–term care facility" means a nursing home licensed under sections 144A.02 to 144A.10, or a boarding care home licensed under sections 144.50 to 144.56. Facilities not certified under title XIX of the federal Social Security Act are not included in this definition.

(d) "Original dispensing pharmacy" shall mean a pharmacy, licensed in any state in the United States, which dispenses drugs in bulk prescription containers to a person who is a resident in a long–term care facility.

Subd. 3. **Authorization to administer and repackage drugs.** (a) A contract pharmacist or pharmacy may repackage a resident's prescription drugs, which have been lawfully dispensed from bulk prescription containers by an original dispensing pharmacy, into a unit–dose system compatible with the system used by the long–term care facility.

(b) A long–term care facility may administer drugs to residents of the facility that have been repackaged according to this subdivision. The contract pharmacy shall notify the long–term care facility whenever medications have been dispensed according to this subdivision and must certify that the repackaging and dispensing has been done in accordance with this subdivision.

(c) Drugs may be dispensed for a resident of a long–term care facility according to this subdivision, provided that:

(1) the drug is dispensed by the original dispensing pharmacy according to a current, valid prescription;

(2) the original bulk prescription container for the resident is delivered by the original dispensing pharmacy directly to the contract pharmacist or pharmacy;

(3) the contract pharmacist or pharmacy verifies the name and strength of the drug, the name of the manufacturer of the drug, the manufacturer's lot or control number, the manufacturer's expiration date for the drug, and the date the drug was dispensed by the original dispensing pharmacy;

(4) the contract pharmacist or pharmacy verifies the validity and accuracy of the current prescription order;

(5) the contract pharmacist or pharmacy repackages the drug in board–approved unit–dose packaging, with labeling that complies with Minnesota Rules, part 6800.6300, and that identifies that the drug has been repackaged according to this section;

(6) the resident for whom the medication is repackaged obtains medications from or receives medications at a discounted rate from the original dispensing pharmacy under the resident's state or federal health assistance program or a private health insurance plan; and

(7) the resident for whom the medication is to be repackaged, or the resident's authorized representative, has signed an informed consent form provided by the facility which includes an explanation of the repackaging process and which notifies the resident of the immunities from liability provided in this section.

Subd. 4. **Maintenance of records.** For each drug repackaged by a contract pharmacy under this section, the contract pharmacy shall maintain a record for at least two years of the following information:

(1) the name, manufacturer, manufacturer's lot number, manufacturer's expiration date, and quantity of the drug prescribed;

(2) the name and address of the resident for whom the drug was repackaged;

(3) the name and address or other identifier of the prescriber;

(4) the date the prescription was issued and the date the drug was repackaged;

(5) the date the repackaged drug was delivered to the long–term care facility;

(6) the directions for use;

(7) a copy of the label that was affixed to the repackaged drug;

(8) the initials of the packager;

(9) the initials of the supervising pharmacist; and

(10) the name and business address of the original dispensing pharmacy.

Subd. 5. **Duties of the original dispensing pharmacy.** Upon request of the resident, the resident's authorized representative, or a contract pharmacy or licensed health care facility acting on behalf of the resident, the original dispensing pharmacy is required to deliver medications dispensed for the resident directly to the contract pharmacist or pharmacy. The original dispensing pharmacy is further required to provide the contract pharmacist or pharmacy with the name and strength of the drug, the name of the manufacturer of the drug, the manufacturer's lot or control number, the manufacturer's expiration date for the drug, and the date the drug was dispensed.

Subd. 6. **Redispensing of returned drugs prohibited.** Unused drugs repackaged according to this section that are returned to any pharmacy shall not be redispensed.

Subd. 7. **Immunity from civil liability.** (a) A contract pharmacist or pharmacy and its employees or agents repackaging a drug acquired from an original dispensing pharmacy shall be immune from civil liability arising from harm caused by the drug due to acts or omissions of other persons outside of the contract pharmacist or pharmacy if the contract pharmacist or pharmacy properly repackages the drug according to this section.

(b) A long–term care facility and the facility's employees or agents who properly administer a drug repackaged by a contract pharmacist or pharmacy under this section shall be immune from civil liability arising from harm caused by the drug due to acts or omissions of other persons outside the long–term care facility.

Subd. 8. **Handling fee.** A contract pharmacist or pharmacy may charge a monthly fee of no more than 250 percent of the medical assistance program dispensing fee for each drug repackaged according to this section, but no more than $100 per month for each individual resident.

History: *2007 c 147 art 11 s 5*

151.56 COUNTY RETURN OF UNUSED DRUGS OR MEDICAL DEVICES.

Notwithstanding Minnesota Rules, part 6800.2700, pharmacies may accept returns of unused drugs and medical devices from county jails and juvenile correctional facilities. In order to return unused drugs and medical devices, the county jail or juvenile correctional facility must have a trained medication technician on hand 24 hours a day, seven days a week, and the medication must be stored in a secured locked storage locker.

History: *2007 c 103 s 4*