CHAPTER 151

PHARMACY

BOARD OF PHARMACY

151.01 DEFINITIONS.

Subdivision 1. **Words, terms, and phrases.** Unless the language or context clearly indicates that a different meaning is intended, the following words, terms, and phrases, for the purposes of this chapter, shall be given the meanings subjoined to them.

Subd. 2. **Pharmacy.** "Pharmacy" means a place of business in which prescription drugs are prepared, compounded, or dispensed by or under the supervision of a pharmacist and from which related clinical pharmacy services are delivered.

Subd. 2a. **Limited service pharmacy.** "Limited service pharmacy" means a pharmacy that has been issued a restricted license by the board to perform a limited range of the activities that constitute the practice of pharmacy.

Subd. 3. **Pharmacist.** "Pharmacist" means an individual with a currently valid license issued by the Board of Pharmacy to practice pharmacy.

Subd. 4. [Repealed, 1988 c 550 s 20]

Subd. 5. **Drug.** "Drug" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof; biological products, other than blood or blood components; all substances and preparations intended for external and internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; and all substances and preparations, other than food, intended to affect the structure or any function of the bodies of humans or other animals. The term drug shall also mean any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and, when introduced into the body, induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

Subd. 6. **Medicine.** "Medicine" means any remedial agent that has the property of curing, preventing, treating, or mitigating diseases, or that is used for that purpose.

Subd. 7. **Poisons.** "Poisons" means any substance that, when introduced into the system, directly or by absorption, produces violent, morbid, or fatal changes, or that destroys living tissue with which it comes in contact.

Subd. 8. **Chemical.** "Chemical" means all medicinal or industrial substances, whether simple or compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

Subd. 9. **Board or Board of Pharmacy.** "Board" or "Board of Pharmacy" means the Minnesota Board of Pharmacy.

Subd. 10. **Director.** "Director" means the executive director of the Minnesota Board of Pharmacy.

Subd. 11. **Person.** "Person" means an individual, firm, partnership, company, corporation, trustee, association, agency, or other public or private entity.

Subd. 12. **Wholesale.** "Wholesale" means and includes any sale for the purpose of resale.

Subd. 13. **Commercial purposes.** "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce, exclusive of the practices of medicine, pharmacy, and other health care professions.

Subd. 14. **Manufacturing.** "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis. Manufacturing includes the packaging or repackaging of a drug, or the labeling or relabeling of the container of a drug, for resale by pharmacies, practitioners, or other persons. Manufacturing does not include the prepackaging, extemporaneous compounding, or anticipatory compounding of a drug within a licensed pharmacy or by a practitioner, nor the labeling of a container within a pharmacy or by a practitioner for the purpose of dispensing a drug to a patient pursuant to a valid prescription.

Subd. 14a. **Manufacturer.** "Manufacturer" means any person engaged in manufacturing.

Subd. 14b. **Outsourcing facility.** "Outsourcing facility" means a facility that is registered by the United States Food and Drug Administration pursuant to United States Code, title 21, section 353b.

Subd. 15. **Pharmacist intern.** "Pharmacist intern" means (1) a natural person satisfactorily progressing toward the degree in pharmacy required for licensure, or (2) a graduate of the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board, who is registered by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist, or (3) a qualified applicant awaiting examination for licensure.

Subd. 15a. **Pharmacy technician.** "Pharmacy technician" means a person not licensed as a pharmacist or registered as a pharmacist intern, who has been trained in pharmacy tasks that do not require the professional judgment of a licensed pharmacist. A pharmacy technician may not perform tasks specifically reserved to a licensed pharmacist.

Subd. 16. **Prescription drug order.** "Prescription drug order" means a lawful written, oral, or electronic order of a practitioner for a drug for a specific patient. Prescription drug orders for controlled substances must be prepared in accordance with the provisions of section 152.11 and the federal Controlled Substances Act and the regulations promulgated thereunder.

Subd. 16a. **Prescription.** "Prescription" means a prescription drug order that is written or printed on paper, an oral order reduced to writing by a pharmacist, or an electronic order. To be valid, a prescription must be issued for an individual patient by a practitioner within the scope and usual course of the practitioner's practice, and must contain the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, the name and address of the practitioner, and a telephone number at which the practitioner can be reached. A prescription written or printed on paper that is given to the patient or an agent of the patient or that is transmitted by fax must contain the practitioner's manual signature. An electronic prescription must contain the practitioner's electronic signature.

Subd. 16b. **Chart order.** "Chart order" means a prescription drug order for a drug that is to be dispensed by a pharmacist, or by a pharmacist intern under the direct supervision of a pharmacist, and administered by an authorized person only during the patient's stay in a hospital or long-term care facility. The chart order shall contain the name of the patient, another patient identifier such as birth date or medical record number, the drug ordered, and any directions that the practitioner may prescribe concerning strength, dosage, frequency, and route of administration. The manual or electronic signature of the practitioner must be affixed to the chart order at the time it is written or at a later date in the case of verbal chart orders.

Subd. 17. **Legend drug.** "Legend drug" means a drug that is required by federal law to be dispensed only pursuant to the prescription of a licensed practitioner.

Subd. 18. **Label.** "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or medicine. Any word, statement, or other information required by or under the authority of this chapter to appear on the label shall also appear on the outside container or wrapper, if any there be, of the retail package of such drug or medicine, or be easily legible through the outside container or wrapper.

Subd. 19. **Package.** "Package" means any container or wrapping in which any drug or medicine is enclosed for use in the delivery or display of that article to retail purchasers, but does not include:

(a) shipping containers or wrappings used solely for the transportation of any such article in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(b) shipping containers or outer wrappings used by retailers to ship or deliver any such article to retail customers if such containers and wrappings bear no printed matter pertaining to any particular drug or medicine.

Subd. 20. **Labeling.** "Labeling" means all labels and other written, printed, or graphic matter (a) upon a drug or medicine or any of its containers or wrappers, or (b) accompanying such article.

Subd. 21. **Federal act.** "Federal act" means the Federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 301, et seq., as amended.

Subd. 22. **Pharmacist in charge.** "Pharmacist in charge" means a duly licensed pharmacist in the state of Minnesota who has been designated in accordance with the rules of the Board of Pharmacy to assume professional responsibility for the operation of the pharmacy in compliance with the requirements and duties as established by the board in its rules.

Subd. 23. **Practitioner.** "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathic medicine duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, or licensed advanced practice registered nurse. For purposes of sections 151.15, subdivision 4; 151.252, subdivision 3; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A. For purposes of sections 151.15, subdivision 4; 151.252, subdivision 3; 151.37, subdivision 2, paragraph (b); and 151.461, "practitioner" also means a dental therapist authorized to dispense and administer under chapter 150A.

Subd. 24. **Brand name.** "Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler or distributor.

Subd. 25. **Generic name.** "Generic name" means the established name or official name of a drug or drug product.

Subd. 26. **Finished dosage form.** "Finished dosage form" means that form of a drug that is or is intended to be dispensed or administered to the patient and requires no further manufacturing or processing other than packaging, reconstitution, or labeling.

Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:

(1) interpretation and evaluation of prescription drug orders;

(2) compounding, labeling, and dispensing drugs and devices (except labeling by a manufacturer or packager of nonprescription drugs or commercially packaged legend drugs and devices);

(3) participation in clinical interpretations and monitoring of drug therapy for assurance of safe and effective use of drugs, including the performance of laboratory tests that are waived under the federal Clinical Laboratory Improvement Act of 1988, United States Code, title 42, section 263a et seq., provided that a pharmacist may interpret the results of laboratory tests but may modify drug therapy only pursuant to a protocol or collaborative practice agreement;

(4) participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; drug regimen reviews; and drug or drug-related research;

(5) participation in administration of influenza vaccines to all eligible individuals six years of age and older and all other vaccines to patients 13 years of age and older by written protocol with a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice registered nurse authorized to prescribe drugs under section 148.235, provided that:

(i) the protocol includes, at a minimum:

(A) the name, dose, and route of each vaccine that may be given;

(B) the patient population for whom the vaccine may be given;

(C) contraindications and precautions to the vaccine;

(D) the procedure for handling an adverse reaction;

(E) the name, signature, and address of the physician, physician assistant, or advanced practice registered nurse;

(F) a telephone number at which the physician, physician assistant, or advanced practice registered nurse can be contacted; and

(G) the date and time period for which the protocol is valid;

(ii) the pharmacist has successfully completed a program approved by the Accreditation Council for Pharmacy Education specifically for the administration of immunizations or a program approved by the board;

(iii) the pharmacist utilizes the Minnesota Immunization Information Connection to assess the immunization status of individuals prior to the administration of vaccines, except when administering influenza vaccines to individuals age nine and older;

(iv) the pharmacist reports the administration of the immunization to the Minnesota Immunization Information Connection; and

(v) the pharmacist complies with guidelines for vaccines and immunizations established by the federal Advisory Committee on Immunization Practices, except that a pharmacist does not need to comply with those portions of the guidelines that establish immunization schedules when administering a vaccine pursuant to a valid, patient-specific order issued by a physician licensed under chapter 147, a physician assistant authorized to prescribe drugs under chapter 147A, or an advanced practice nurse authorized to prescribe drugs under section 148.235, provided that the order is consistent with the United States Food and Drug Administration approved labeling of the vaccine;

(6) participation in the initiation, management, modification, and discontinuation of drug therapy according to a written protocol or collaborative practice agreement between: (i) one or more pharmacists and one or more dentists, optometrists, physicians, podiatrists, or veterinarians; or (ii) one or more pharmacists and one or more physician assistants authorized to prescribe, dispense, and administer under chapter 147A, or advanced practice nurses authorized to prescribe, dispense, and administer under section 148.235. Any changes in drug therapy made pursuant to a protocol or collaborative practice agreement must be documented by the pharmacist in the patient's medical record or reported by the pharmacist to a practitioner responsible for the patient's care;

(7) participation in the storage of drugs and the maintenance of records;

(8) patient counseling on therapeutic values, content, hazards, and uses of drugs and devices;

(9) offering or performing those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a pharmacy; and

(10) participation in the initiation, management, modification, and discontinuation of therapy with opiate antagonists, as defined in section 604A.04, subdivision 1, pursuant to:

(i) a written protocol as allowed under clause (6); or

(ii) a written protocol with a community health board medical consultant or a practitioner designated by the commissioner of health, as allowed under section 151.37, subdivision 13.

Subd. 27a. **Protocol.** "Protocol" means:

(1) a specific written plan that describes the nature and scope of activities that a pharmacist may engage in when initiating, managing, modifying, or discontinuing drug therapy as allowed in subdivision 27, clause (6); or

(2) a specific written plan that authorizes a pharmacist to administer vaccines and that complies with subdivision 27, clause (5).

Subd. 27b. **Collaborative practice.** "Collaborative practice" means patient care activities, consistent with subdivision 27, engaged in by one or more pharmacists who have agreed to work in collaboration with one or more practitioners to initiate, manage, and modify drug therapy under specified conditions mutually agreed to by the pharmacists and practitioners.

Subd. 27c. **Collaborative practice agreement.** "Collaborative practice agreement" means a written and signed agreement between one or more pharmacists and one or more practitioners that allows the pharmacist or pharmacists to engage in collaborative practice.

Subd. 28. **Veterinary legend drug.** "Veterinary legend drug" means a drug that is required by federal law to be dispensed only pursuant to the prescription of a licensed veterinarian.

Subd. 29. **Legend medical gas.** "Legend medical gas" means a liquid or gaseous substance used for medical purposes and that is required by federal law to be dispensed only pursuant to the prescription of a licensed practitioner.

Subd. 30. **Dispense or dispensing.** "Dispense or dispensing" means the interpretation, evaluation, and processing of a prescription drug order and includes those processes specified by the board in rule that are necessary for the preparation and provision of a drug to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

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.

Subd. 34. **Health professional shortage area.** "Health professional shortage area" means an area designated as such by the federal Secretary of Health and Human Services, as provided under Code of Federal Regulations, title 42, part 5, and United States Code, title 42, section 254E.

Subd. 35. **Compounding.** "Compounding" means preparing, mixing, assembling, packaging, and labeling a drug for an identified individual patient as a result of a practitioner's prescription drug order. Compounding also includes anticipatory compounding, as defined in this section, and the preparation of drugs in which all bulk drug substances and components are nonprescription substances. Compounding does not include mixing or reconstituting a drug according to the product's labeling or to the manufacturer's directions. Compounding does not include the preparation of a drug for the purpose of, or incident to, research, teaching, or chemical analysis, provided that the drug is not prepared for dispensing or administration to patients. All compounding, regardless of the type of product, must be done pursuant to a prescription drug order unless otherwise permitted in this chapter or by the rules of the board. Compounding does not include a minor deviation from such directions with regard to radioactivity, volume, or stability, which is made by or under the supervision of a licensed nuclear pharmacist or a physician, and which is necessary in order to accommodate circumstances not contemplated in the manufacturer's instructions, such as the rate of radioactive decay or geographical distance from the patient.

Subd. 36. **Anticipatory compounding.** "Anticipatory compounding" means the preparation by a pharmacy of a supply of a compounded drug product that is sufficient to meet the short-term anticipated need of the pharmacy for the filling of prescription drug orders. In the case of practitioners only, anticipatory compounding means the preparation of a supply of a compounded drug product that is sufficient to meet the practitioner's short-term anticipated need for dispensing or administering the drug to patients treated by the practitioner. Anticipatory compounding is not the preparation of a compounded drug product for wholesale distribution.

Subd. 37. **Extemporaneous compounding.** "Extemporaneous compounding" means the compounding of a drug product pursuant to a prescription drug order for a specific patient that is issued in advance of the compounding. Extemporaneous compounding is not the preparation of a compounded drug product for wholesale distribution.

Subd. 38. **Compounded positron emission tomography drug.** "Compounded positron emission tomography drug" means a drug that:

(1) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images;

(2) has been compounded by or on the order of a practitioner in accordance with the relevant parts of Minnesota Rules, chapters 4731 and 6800, for a patient or for research, teaching, or quality control; and

(3) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

Subd. 39. **Ultimate user.** "Ultimate user" means a natural person who possesses a legend drug that was lawfully obtained for personal use or for the use of a household member or for the use of an animal owned by the natural person or by a household member.

Subd. 40. **Biological product.** "Biological product" has the meaning provided in United States Code, title 42, section 262.

Subd. 41. **Interchangeable biological product.** "Interchangeable biological product" means a biological product that the U.S. Food and Drug Administration has:

(1) licensed, and determined to meet the standards for "interchangeability" under United States Code, title 42, section 262(k)(4); or

(2) determined to be therapeutically equivalent, as set forth in the most recent edition or supplement of the U.S. Food and Drug Administration publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

History: *(5808-1) 1937 c 354 s 1; 1961 c 394 s 1; 1967 c 377 s 1,2; 1969 c 933 s 1-7; 1973 c 639 s 1,2; 1975 c 101 s 1; 1985 c 247 s 25; 1985 c 248 s 70; 1986 c 444; 1988 c 550 s 1-5; 1990 c 412 s 1,2; 1990 c 526 s 2; 1991 c 213 s 1; 1993 c 121 s 10; 1994 c 389 s 3; 1994 c 632 art 2 s 36; 1995 c 205 art 2 s 5; 1997 c 132 s 1; 1999 c 62 s 1; 2003 c 118 s 18; 2007 c 103 s 1; 2007 c 123 s 122,123; 2008 c 189 s 22; 2008 c 321 s 3; 2009 c 95 art 3 s 30; 2009 c 157 art 1 s 12; 2012 c 166 s 1,2; 2014 c 235 s 38; 2014 c 285 s 1; 2014 c 291 art 5 s 1; 2015 c 71 art 10 s 26,27; 2016 c 119 s 7; 2016 c 124 s 1,2; 2017 c 84 s 1-3*

151.02 STATE BOARD OF PHARMACY.

The Minnesota State Board of Pharmacy shall consist of three public members as defined by section 214.02 and six pharmacists actively engaged in the practice of pharmacy in this state. Each of said pharmacists shall have had at least five consecutive years of practical experience as a pharmacist immediately preceding appointment.

History: *(5808-2) 1937 c 354 s 2; 1973 c 638 s 27; 1976 c 239 s 58; 1986 c 444; 2015 c 71 art 10 s 28*

151.03 MEMBERSHIP.

Members of the board shall be appointed by the governor. The governor shall make appointments to the board that reflect the geography of the state. The board members who are pharmacists must, as a whole, reflect the broad mix of practice types of pharmacists practicing in Minnesota. Membership terms, compensation of members, removal of members, the filling of membership vacancies, and fiscal year and reporting requirements shall be as provided in sections 214.07 to 214.09. The provision of staff, administrative

services and office space; the review and processing of complaints; the setting of board fees; and other provisions relating to board operations shall be as provided in chapter 214. Any pharmacist on the board who, during incumbency, ceases to be actively engaged in the practice of pharmacy in this state shall be automatically disqualified from membership.

History: *(5808-3) 1937 c 354 s 3; 1973 c 638 s 28; 1975 c 136 s 29; 1976 c 149 s 32; 1976 c 222 s 80; 1986 c 444; 1991 c 199 art 1 s 45; 1992 c 389 s 1*

151.04 RECOMMENDED NAMES.

The Minnesota State Pharmaceutical Association and the Minnesota Society of Hospital Pharmacists may jointly recommend five names for each pharmacist to be appointed.

History: *(5808-4) 1937 c 354 s 4; 1973 c 638 s 29; 1988 c 550 s 6*

151.05 ELECTION OF OFFICERS.

The board shall annually elect one of its members as president and one of its members as vice-president, and a pharmacist, who may or may not be a member, as secretary.

History: *(5808-5) 1937 c 354 s 5*

151.06 POWERS AND DUTIES.

Subdivision 1. **Generally; rules.** (a) 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 take disciplinary action against any registration or license required under this chapter upon any of the grounds listed in section 151.071, and in accordance with the provisions of section 151.071;

(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;

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

(11) to enter and inspect any business to which it issues a license or registration.

(b) 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 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.

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

Subd. 1a. **Cease and desist orders.** (a) Whenever it appears to the board that a person has engaged in an act or practice constituting a violation of a law, rule, or other order related to the duties and responsibilities entrusted to the board, the board may issue and cause to be served upon the person an order requiring the person to cease and desist from violations.

(b) The cease and desist order must state the reasons for the issuance of the order and must give reasonable notice of the rights of the person to request a hearing before an administrative law judge. A hearing must be held not later than ten days after the request for the hearing is received by the board. After the completion of the hearing, the administrative law judge shall issue a report within ten days. Within 15 days after receiving the report of the administrative law judge, the board shall issue a further order vacating or making permanent the cease and desist order. The time periods provided in this provision may be waived by agreement of the executive director of the board and the person against whom the cease and desist order was issued. If the person to whom a cease and desist order is issued fails to appear at the hearing after being duly notified, the person is in default, and the proceeding may be determined against that person upon consideration of the cease and desist order, the allegations of which may be considered to be true. Unless otherwise provided, all hearings must be conducted according to chapter 14. The board may adopt rules of procedure concerning all proceedings conducted under this subdivision.

(c) If no hearing is requested within 30 days of service of the order, the cease and desist order will become permanent.

(d) A cease and desist order issued under this subdivision remains in effect until it is modified or vacated by the board. The administrative proceeding provided by this subdivision, and subsequent appellate judicial review of that administrative proceeding, constitutes the exclusive remedy for determining whether the board properly issued the cease and desist order and whether the cease and desist order should be vacated or made permanent.

Subd. 1b. **Enforcement of violations of cease and desist orders.** (a) Whenever the board under subdivision 1a seeks to enforce compliance with a cease and desist order that has been made permanent, the allegations of the cease and desist order are considered conclusively established for purposes of proceeding under subdivision 1a for permanent or temporary relief to enforce the cease and desist order. Whenever the board under subdivision 1a seeks to enforce compliance with a cease and desist order when a hearing or hearing request on the cease and desist order is pending, or the time has not yet expired to request a hearing on whether a cease and desist order should be vacated or made permanent, the allegations in the cease and desist order are considered conclusively established for the purposes of proceeding under subdivision 1a for temporary relief to enforce the cease and desist order.

(b) Notwithstanding this subdivision or subdivision 1a, the person against whom the cease and desist order is issued and who has requested a hearing under subdivision 1a may, within 15 days after service of the cease and desist order, bring an action in Ramsey County District Court for issuance of an injunction to suspend enforcement of the cease and desist order pending a final decision of the board under subdivision 1a to vacate or make permanent the cease and desist order. The court shall determine whether to issue such an injunction based on traditional principles of temporary relief.

Subd. 2. **Application.** In the case of a facility licensed or registered by the board, the provisions of subdivision 1 shall apply to an individual owner or sole proprietor and shall also apply to the following:

(1) In the case of a partnership, each partner thereof;

(2) In the case of an association, each member thereof;

(3) In the case of a corporation, each officer or director thereof and each shareholder owning 30 percent or more of the voting stock of such corporation.

Subd. 2a. [Repealed, 1988 c 550 s 20]

Subd. 3. [Repealed by amendment, 2014 c 291 art 5 s 2]

Subd. 4. [Repealed by amendment, 2014 c 291 art 5 s 2]

Subd. 5. [Repealed by amendment, 2014 c 291 art 5 s 2]

History: *(5808-6) 1937 c 354 s 6; 1941 c 78 s 1; 1955 c 847 s 16; 1969 c 933 s 8; 1973 c 722 s 2; 1975 c 136 s 30; 1976 c 222 s 81,82; 1982 c 424 s 130; 1985 c 248 s 70; 1988 c 550 s 7; 1990 c 526 s 3; 1990 c 568 art 2 s 18; 1992 c 513 art 7 s 10,11; 1992 c 577 s 5; 1997 c 132 s 2; 2003 c 66 s 8; 2007 c 123 s 124; 2010 c 289 s 1; 2014 c 285 s 2,3; 2014 c 291 art 5 s 2; 2017 c 40 art 1 s 39*

151.061 UNFAIR PRICE DISCRIMINATION.

Subdivision 1. **Generally.** Any person doing business in this state and engaged in the distribution (other than at retail) of any prescription drugs, who shall discriminate between purchasers by selling prescription drugs at a lower price or rate to one purchaser or association of purchasers than offered to another purchaser or association of purchasers within this state (other than at retail) after making allowance for the difference, if any, in the grade, quality, or quantity, and after equalizing the distance from the point of distribution and freight costs therefrom, shall be guilty of unfair discrimination. Unfair discrimination occurs when quantity discounts are not reasonably based on actual cost savings to all like purchasers. Unfair discrimination shall embrace any scheme of special rebates, collateral contracts, or any device of any nature which in substance violates the provisions of this subdivision. Nothing in this subdivision shall apply to purchases for their own

use by schools, colleges, universities, public libraries, churches, hospitals or charitable institutions not operated for profit.

Subd. 2. **Remedy.** Any person injured by unfair discrimination as defined in subdivision 1 may bring a civil action and recover damages, together with costs and disbursements, including reasonable attorney's fees, and receive other equitable relief as determined by the court. The remedies provided by this section are cumulative and shall not be construed as restricting any remedy which is otherwise available.

History: *1973 c 722 s 1*

151.065 FEE AMOUNTS.

Subdivision 1. **Application fees.** Application fees for licensure and registration are as follows:

(1) pharmacist licensed by examination, $145;

(2) pharmacist licensed by reciprocity, $240;

(3) pharmacy intern, $37.50;

(4) pharmacy technician, $37.50;

(5) pharmacy, $225;

(6) drug wholesaler, legend drugs only, $235;

(7) drug wholesaler, legend and nonlegend drugs, $235;

(8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $210;

(9) drug wholesaler, medical gases, $175;

(10) drug wholesaler, also licensed as a pharmacy in Minnesota, $150;

(11) drug manufacturer, legend drugs only, $235;

(12) drug manufacturer, legend and nonlegend drugs, $235;

(13) drug manufacturer, nonlegend or veterinary legend drugs, $210;

(14) drug manufacturer, medical gases, $185;

(15) drug manufacturer, also licensed as a pharmacy in Minnesota, $150;

(16) medical gas distributor, $110;

(17) controlled substance researcher, $75; and

(18) pharmacy professional corporation, $125.

Subd. 2. **Original license fee.** The pharmacist original licensure fee, $145.

Subd. 3. **Annual renewal fees.** Annual licensure and registration renewal fees are as follows:

(1) pharmacist, $145;

(2) pharmacy technician, $37.50;

(3) pharmacy, $225;

(4) drug wholesaler, legend drugs only, $235;

(5) drug wholesaler, legend and nonlegend drugs, $235;

(6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, $210;

(7) drug wholesaler, medical gases, $185;

(8) drug wholesaler, also licensed as a pharmacy in Minnesota, $150;

(9) drug manufacturer, legend drugs only, $235;

(10) drug manufacturer, legend and nonlegend drugs, $235;

(11) drug manufacturer, nonlegend, veterinary legend drugs, or both, $210;

(12) drug manufacturer, medical gases, $185;

(13) drug manufacturer, also licensed as a pharmacy in Minnesota, $150;

(14) medical gas distributor, $110;

(15) controlled substance researcher, $75; and

(16) pharmacy professional corporation, $75.

Subd. 4. **Miscellaneous fees.** Fees for issuance of affidavits and duplicate licenses and certificates are as follows:

(1) intern affidavit, $20;

(2) duplicate small license, $20; and

(3) duplicate large certificate, $30.

Subd. 5. **Late fees.** All annual renewal fees are subject to a 50 percent late fee if the renewal fee and application are not received by the board prior to the date specified by the board.

Subd. 6. **Reinstatement fees.** (a) A pharmacist who has allowed the pharmacist's license to lapse may reinstate the license with board approval and upon payment of any fees and late fees in arrears, up to a maximum of $1,000.

(b) A pharmacy technician who has allowed the technician's registration to lapse may reinstate the registration with board approval and upon payment of any fees and late fees in arrears, up to a maximum of $90.

(c) An owner of a pharmacy, a drug wholesaler, a drug manufacturer, or a medical gas distributor who has allowed the license of the establishment to lapse may reinstate the license with board approval and upon payment of any fees and late fees in arrears.

(d) A controlled substance researcher who has allowed the researcher's registration to lapse may reinstate the registration with board approval and upon payment of any fees and late fees in arrears.

(e) A pharmacist owner of a professional corporation who has allowed the corporation's registration to lapse may reinstate the registration with board approval and upon payment of any fees and late fees in arrears.

History: *1Sp2011 c 9 art 5 s 17; 2015 c 71 art 10 s 29-32*

151.07 MEETINGS; EXAMINATION FEE.

The board shall meet at times as may be necessary and as it may determine to examine applicants for licensure and to transact its other business, giving reasonable notice of all examinations by mail to known applicants therefor. The secretary shall record the names of all persons licensed by the board, together with the grounds upon which the right of each to licensure was claimed. The fee for examination shall be in the amount specified in section 151.065, which fee may in the discretion of the board be returned to applicants not taking the examination.

History: *(5808-7) 1937 c 354 s 7; 1953 c 76 s 1; 1961 c 394 s 2; 1975 c 136 s 31; 1976 c 222 s 83; 1Sp2011 c 9 art 5 s 18*

151.071 DISCIPLINARY ACTION.

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

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

(2) refuse to renew a license or registration;

(3) revoke the license or registration;

(4) suspend the license or registration;

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

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

(7) reprimand the licensee or registrant.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(17) fee splitting, including without limitation:

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

(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;

(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.

Subd. 3. **Automatic suspension.** (a) A license or registration issued under this chapter to a pharmacist, pharmacist intern, pharmacy technician, or controlled substance researcher is automatically suspended if: (1) a guardian of a licensee or registrant is appointed by order of a court pursuant to sections 524.5-101 to 524.5-502, for reasons other than the minority of the licensee or registrant; or (2) the licensee or registrant is committed by order of a court pursuant to chapter 253B. The license or registration remains suspended until the licensee is restored to capacity by a court and, upon petition by the licensee or registrant, the suspension is terminated by the board after a hearing.

(b) For a pharmacist, pharmacy intern, or pharmacy technician, upon notice to the board of a judgment of, or a plea of guilty to, a felony reasonably related to the practice of pharmacy, the license or registration of the regulated person may be automatically suspended by the board. The license or registration will remain suspended until, upon petition by the regulated individual and after a hearing, the suspension is terminated by the board. The board may indefinitely suspend or revoke the license or registration of the regulated individual if, after a hearing before the board, the board finds that the felonious conduct would cause a serious risk of harm to the public.

(c) For a facility that is licensed or registered by the board, upon notice to the board that an owner of the facility is subject to a judgment of, or a plea of guilty to, a felony reasonably related to the operation of the facility, the license or registration of the facility may be automatically suspended by the board. The license or registration will remain suspended until, upon petition by the facility and after a hearing, the suspension is terminated by the board. The board may indefinitely suspend or revoke the license or registration of the facility if, after a hearing before the board, the board finds that the felonious conduct would cause a serious risk of harm to the public.

(d) For licenses and registrations that have been suspended or revoked pursuant to paragraphs (a) and (b), the regulated individual may have a license or registration reinstated, either with or without restrictions, by demonstrating clear and convincing evidence of rehabilitation, as provided in section 364.03. If the regulated individual has the conviction subsequently overturned by court decision, the board shall conduct a hearing to review the suspension within 30 days after the receipt of the court decision. The regulated individual is not required to prove rehabilitation if the subsequent court decision overturns previous court findings of public risk.

(e) For licenses and registrations that have been suspended or revoked pursuant to paragraph (c), the regulated facility may have a license or registration reinstated, either with or without restrictions, conditions, or limitations, by demonstrating clear and convincing evidence of rehabilitation of the convicted owner, as provided in section 364.03. If the convicted owner has the conviction subsequently overturned by court decision, the board shall conduct a hearing to review the suspension within 30 days after receipt of the court decision. The regulated facility is not required to prove rehabilitation of the convicted owner if the subsequent court decision overturns previous court findings of public risk.

(f) The board may, upon majority vote of a quorum of its appointed members, suspend the license or registration of a regulated individual without a hearing if the regulated individual fails to maintain a current name and address with the board, as described in paragraphs (h) and (i), while the regulated individual is: (1) under board investigation, and a notice of conference has been issued by the board; (2) party to a contested case with the board; (3) party to an agreement for corrective action with the board; or (4) under a board order for disciplinary action. The suspension shall remain in effect until lifted by the board to the board's receipt of a petition from the regulated individual, along with the current name and address of the regulated individual.

(g) The board may, upon majority vote of a quorum of its appointed members, suspend the license or registration of a regulated facility without a hearing if the regulated facility fails to maintain a current name and address of the owner of the facility with the board, as described in paragraphs (h) and (i), while the regulated facility is: (1) under board investigation, and a notice of conference has been issued by the board; (2) party to a contested case with the board; (3) party to an agreement for corrective action with the board; or (4) under a board order for disciplinary action. The suspension shall remain in effect until lifted by the board pursuant to the board's receipt of a petition from the regulated facility, along with the current name and address of the owner of the facility.

(h) An individual licensed or registered by the board shall maintain a current name and home address with the board and shall notify the board in writing within 30 days of any change in name or home address. An individual regulated by the board shall also maintain a current business address with the board as required by section 214.073. For an individual, if a name change only is requested, the regulated individual must request a revised license or registration. The board may require the individual to substantiate the name change by submitting official documentation from a court of law or agency authorized under law to receive and officially record a name change. In the case of an individual, if an address change only is requested, no

request for a revised license or registration is required. If the current license or registration of an individual has been lost, stolen, or destroyed, the individual shall provide a written explanation to the board.

(i) A facility licensed or registered by the board shall maintain a current name and address with the board. A facility shall notify the board in writing within 30 days of any change in name. A facility licensed or registered by the board but located outside of the state must notify the board within 30 days of an address change. A facility licensed or registered by the board and located within the state must notify the board at least 60 days in advance of a change of address that will result from the move of the facility to a different location and must pass an inspection at the new location as required by the board. If the current license or registration of a facility has been lost, stolen, or destroyed, the facility shall provide a written explanation to the board.

Subd. 4. **Effective dates.** A suspension, revocation, condition, limitation, qualification, or restriction of a license or registration shall be in effect pending determination of an appeal. A revocation of a license pursuant to subdivision 1 is not appealable and shall remain in effect indefinitely.

Subd. 5. **Conditions on reissued license.** In its discretion, the board may restore and reissue a license or registration issued under this chapter, but as a condition thereof may impose any disciplinary or corrective measure that it might originally have imposed.

Subd. 6. **Temporary suspension of license for pharmacists.** In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend the license of a pharmacist if the board finds that the pharmacist has violated a statute or rule that the board is empowered to enforce and continued practice by the pharmacist would create a serious risk of harm to the public. The suspension shall take effect upon written notice to the pharmacist, specifying the statute or rule violated. The suspension shall remain in effect until the board issues a final order in the matter after a hearing. At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held pursuant to the Administrative Procedure Act. The pharmacist shall be provided with at least 20 days' notice of any hearing held pursuant to this subdivision. The hearing shall be scheduled to begin no later than 30 days after the issuance of the suspension order.

Subd. 7. **Temporary suspension of license for pharmacist interns, pharmacy technicians, and controlled substance researchers.** In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend the registration of a pharmacist intern, pharmacy technician, or controlled substance researcher if the board finds that the registrant has violated a statute or rule that the board is empowered to enforce and continued registration of the registrant would create a serious risk of harm to the public. The suspension shall take effect upon written notice to the registrant, specifying the statute or rule violated. The suspension shall remain in effect until the board issues a final order in the matter after a hearing. At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held pursuant to the Administrative Procedure Act. The licensee or registrant shall be provided with at least 20 days' notice of any hearing held pursuant to this subdivision. The hearing shall be scheduled to begin no later than 30 days after the issuance of the suspension order.

Subd. 8. **Temporary suspension of license for pharmacies, drug wholesalers, drug manufacturers, medical gas manufacturers, and medical gas distributors.** In addition to any other remedy provided by law, the board may, without a hearing, temporarily suspend the license or registration of a pharmacy, drug wholesaler, drug manufacturer, medical gas manufacturer, or medical gas distributor if the board finds that the licensee or registrant has violated a statute or rule that the board is empowered to enforce and continued operation of the licensed facility would create a serious risk of harm to the public. The suspension shall take effect upon written notice to the licensee or registrant, specifying the statute or rule violated. The suspension

shall remain in effect until the board issues a final order in the matter after a hearing. At the time it issues the suspension notice, the board shall schedule a disciplinary hearing to be held pursuant to the Administrative Procedure Act. The licensee or registrant shall be provided with at least 20 days' notice of any hearing held pursuant to this subdivision. The hearing shall be scheduled to begin no later than 30 days after the issuance of the suspension order.

Subd. 9. **Evidence.** In disciplinary actions alleging a violation of subdivision 2, clause (4), (5), (6), or (7), a copy of the judgment or proceeding under the seal of the court administrator or of the administrative agency that entered the same shall be admissible into evidence without further authentication and shall constitute prima facie evidence of the contents thereof.

Subd. 10. **Mental examination; access to medical data.** (a) If the board receives a complaint and has probable cause to believe that an individual licensed or registered by the board falls under subdivision 2, clause (14), it may direct the individual to submit to a mental or physical examination. For the purpose of this subdivision, every licensed or registered individual is deemed to have consented to submit to a mental or physical examination when directed in writing by the board and further to have waived all objections to the admissibility of the examining practitioner's testimony or examination reports on the grounds that the same constitute a privileged communication. Failure of a licensed or registered individual to submit to an examination when directed constitutes an admission of the allegations against the individual, unless the failure was due to circumstances beyond the individual's control, in which case a default and final order may be entered without the taking of testimony or presentation of evidence. Pharmacists affected under this paragraph shall at reasonable intervals be given an opportunity to demonstrate that they can resume the competent practice of the profession of pharmacy with reasonable skill and safety to the public. Pharmacist interns, pharmacy technicians, or controlled substance researchers affected under this paragraph shall at reasonable intervals be given an opportunity to demonstrate that they can competently resume the duties that can be performed, under this chapter or the rules of the board, by similarly registered persons with reasonable skill and safety to the public. In any proceeding under this paragraph, neither the record of proceedings nor the orders entered by the board shall be used against a licensed or registered individual in any other proceeding.

(b) Notwithstanding section 13.384, 144.651, or any other law limiting access to medical or other health data, the board may obtain medical data and health records relating to an individual licensed or registered by the board, or to an applicant for licensure or registration, without the individual's consent when the board receives a complaint and has probable cause to believe that the individual is practicing in violation of subdivision 2, clause (14), and the data and health records are limited to the complaint. The medical data may be requested from a provider, as defined in section 144.291, subdivision 2, paragraph (h), an insurance company, or a government agency, including the Department of Human Services. A provider, insurance company, or government agency shall comply with any written request of the board under this subdivision and is not liable in any action for damages for releasing the data requested by the board if the data are released pursuant to a written request under this subdivision, unless the information is false and the provider giving the information knew, or had reason to believe, the information was false. Information obtained under this subdivision is classified as private under sections 13.01 to 13.87.

Subd. 11. **Tax clearance certificate.** (a) In addition to the provisions of subdivision 1, the board may not issue or renew a license or registration if the commissioner of revenue notifies the board and the licensee or applicant for a license that the licensee or applicant owes the state delinquent taxes in the amount of $500 or more. The board may issue or renew the license or registration only if (1) the commissioner of revenue issues a tax clearance certificate, and (2) the commissioner of revenue or the licensee, registrant, or applicant

forwards a copy of the clearance to the board. The commissioner of revenue may issue a clearance certificate only if the licensee, registrant, or applicant does not owe the state any uncontested delinquent taxes.

(b) For purposes of this subdivision, the following terms have the meanings given.

(1) "Taxes" are all taxes payable to the commissioner of revenue, including penalties and interest due on those taxes.

(2) "Delinquent taxes" do not include a tax liability if (i) an administrative or court action that contests the amount or validity of the liability has been filed or served, (ii) the appeal period to contest the tax liability has not expired, or (iii) the licensee or applicant has entered into a payment agreement to pay the liability and is current with the payments.

(c) In lieu of the notice and hearing requirements of subdivision 1, when a licensee, registrant, or applicant is required to obtain a clearance certificate under this subdivision, a contested case hearing must be held if the licensee or applicant requests a hearing in writing to the commissioner of revenue within 30 days of the date of the notice provided in paragraph (a). The hearing must be held within 45 days of the date the commissioner of revenue refers the case to the Office of Administrative Hearings. Notwithstanding any law to the contrary, the licensee or applicant must be served with 20 days' notice in writing specifying the time and place of the hearing and the allegations against the licensee or applicant. The notice may be served personally or by mail.

(d) A licensee or applicant must provide the licensee's or applicant's Social Security number and Minnesota business identification number on all license applications. Upon request of the commissioner of revenue, the board must provide to the commissioner of revenue a list of all licensees and applicants that includes the licensee's or applicant's name, address, Social Security number, and business identification number. The commissioner of revenue may request a list of the licensees and applicants no more than once each calendar year.

Subd. 12. **Limitation.** No board proceeding against a regulated person or facility shall be instituted unless commenced within seven years from the date of the commission of some portion of the offense or misconduct complained of except for alleged violations of subdivision 2, clause (21).

History: *2014 c 291 art 5 s 3*

151.072 REPORTING OBLIGATIONS.

Subdivision 1. **Permission to report.** A person who has knowledge of any conduct constituting grounds for discipline under the provisions of this chapter or the rules of the board may report the violation to the board.

Subd. 2. **Pharmacies.** A pharmacy located in this state must report to the board any discipline that is related to an incident involving conduct that would constitute grounds for discipline under the provisions of this chapter or the rules of the board, that is taken by the pharmacy or any of its administrators against a pharmacist, pharmacist intern, or pharmacy technician, including the termination of employment of the individual or the revocation, suspension, restriction, limitation, or conditioning of an individual's ability to practice or work at or on behalf of the pharmacy. The pharmacy shall also report the resignation of any pharmacist, pharmacist intern, or technician prior to the conclusion of any disciplinary proceeding, or prior to the commencement of formal charges but after the individual had knowledge that formal charges were contemplated or in preparation. Each report made under this subdivision must state the nature of the action taken and state in detail the reasons for the action. Failure to report violations as required by this subdivision is a basis for discipline pursuant to section 151.071, subdivision 2, clause (8).

Subd. 3. **Licensees and registrants of the board.** A licensee or registrant of the board shall report to the board personal knowledge of any conduct that the person reasonably believes constitutes grounds for disciplinary action under this chapter or the rules of the board by any pharmacist, pharmacist intern, pharmacy technician, or controlled substance researcher, including any conduct indicating that the person may be professionally incompetent, or may have engaged in unprofessional conduct or may be medically or physically unable to engage safely in the practice of pharmacy or to carry out the duties permitted to the person by this chapter or the rules of the board. Failure to report violations as required by this subdivision is a basis for discipline pursuant to section 151.071, subdivision 2, clause (20).

Subd. 4. **Self-reporting.** A licensee or registrant of the board shall report to the board any personal action that would require that a report be filed with the board pursuant to subdivision 2.

Subd. 5. **Deadlines; forms.** Reports required by subdivisions 2 to 4 must be submitted not later than 30 days after the occurrence of the reportable event or transaction. The board may provide forms for the submission of reports required by this section, may require that reports be submitted on the forms provided, and may adopt rules necessary to assure prompt and accurate reporting.

Subd. 6. **Subpoenas.** The board may issue subpoenas for the production of any reports required by subdivisions 2 to 4 or any related documents.

History: *2014 c 291 art 5 s 4*

151.073 IMMUNITY.

Subdivision 1. **Reporting.** Any person, health care facility, business, or organization is immune from civil liability or criminal prosecution for submitting in good faith a report to the board under section 151.072 or for otherwise reporting in good faith to the board violations or alleged violations of this chapter or the rules of the board. All such reports are investigative data as defined in chapter 13.

Subd. 2. **Investigation.** (a) Members of the board and persons employed by the board or engaged on behalf of the board in the investigation of violations and in the preparation and management of charges or violations of this chapter or the rules of the board, or persons participating in the investigation or testifying regarding charges of violations, when acting in good faith, are immune from civil liability for any actions, transactions, or publications in the execution of, or relating to, their duties under this chapter or the rules of the board.

(b) Members of the board and persons employed by the board or engaged in maintaining records and making reports regarding adverse health care events are immune from civil liability for any actions, transactions, or publications in the execution of, or relating to, their duties under section 151.301.

History: *2014 c 291 art 5 s 5*

151.074 LICENSEE OR REGISTRANT COOPERATION.

An individual who is licensed or registered by the board, who is the subject of an investigation by or on behalf of the board, shall cooperate fully with the investigation. An owner or employee of a facility that is licensed or registered by the board, when the facility is the subject of an investigation by or on behalf of the board, shall cooperate fully with the investigation. Cooperation includes responding fully and promptly to any question raised by, or on behalf of, the board relating to the subject of the investigation and providing copies of patient pharmacy records and other relevant records, as reasonably requested by the board, to assist

the board in its investigation. The board shall maintain any records obtained pursuant to this section as investigative data pursuant to chapter 13.

History: *2014 c 291 art 5 s 6*

151.075 DISCIPLINARY RECORD ON JUDICIAL REVIEW.

Upon judicial review of any board disciplinary action taken under this chapter, the reviewing court shall seal the administrative record, except for the board's final decision, and shall not make the administrative record available to the public.

History: *2014 c 291 art 5 s 7*

151.08 [Repealed, 1975 c 136 s 77]

151.09 [Repealed, 1976 c 222 s 209]

151.095 INACTIVE STATUS LICENSE.

The board may, by rule, establish standards for an inactive status of licensure for previously licensed pharmacists who have retired from active practice, have left the state, or have otherwise ceased to be actively engaged in the practice of pharmacy in this state.

History: *1988 c 550 s 8*

151.10 QUALIFICATIONS OF APPLICANTS.

Subdivision 1. **Graduates of schools in good standing.** To be entitled to examination by the board as a pharmacist the applicant shall be of good moral character, at least 18 years of age, and shall be a graduate of the College of Pharmacy of the University of Minnesota or of a college or school of pharmacy in good standing of which the board shall be the judge and shall have completed internship requirements as prescribed by the board.

Subd. 2. **Graduates of schools outside the United States.** An applicant who is a graduate of a school or college of pharmacy located outside the United States, when that school or college of pharmacy has not been recognized by the board as a school in good standing, may be entitled to examination for licensure by the board if the applicant is of good moral character, at least 18 years of age, has completed the internship requirements prescribed by the board, has provided verification of the applicant's academic record and graduation, and has successfully passed examinations approved by the board to establish proficiency in English and equivalency of education with graduates of schools or colleges of pharmacy which the board has determined to be in good standing.

History: *(5808-10) 1937 c 354 s 10; 1941 c 78 s 2; 1973 c 639 s 3; 1973 c 725 s 20; 1976 c 222 s 84; 1984 c 426 s 1; 1986 c 444*

151.101 INTERNSHIP.

Upon payment of the fee specified in section 151.065, the board may register as an intern any natural persons who have satisfied the board that they are of good moral character, not physically or mentally unfit, and who have successfully completed the educational requirements for intern registration prescribed by the board. The board shall prescribe standards and requirements for interns, pharmacist-preceptors, and internship training but may not require more than one year of such training.

The board in its discretion may accept internship experience obtained in another state provided the internship requirements in such other state are in the opinion of the board equivalent to those herein provided.

History: *1969 c 933 s 9; 1973 c 639 s 4; 1976 c 222 s 85; 1986 c 444; 1988 c 550 s 9; 1Sp2011 c 9 art 5 s 19*

151.102 PHARMACY TECHNICIAN.

Subdivision 1. **General.** A pharmacy technician may assist a pharmacist in the practice of pharmacy by performing tasks that are not reserved to, and do not require the professional judgment of, a licensed pharmacist. A pharmacy technician works under the personal and direct supervision of the pharmacist. A pharmacist may supervise up to three technicians. A pharmacist is responsible for all the work performed by the technicians who are under the supervision of the pharmacist. A pharmacy may exceed the ratio of pharmacy technicians to pharmacists permitted in this subdivision or in rule by a total of one technician at any given time in the pharmacy, provided at least one technician in the pharmacy holds a valid certification from the Pharmacy Technician Certification Board or from another national certification body for pharmacy technicians that requires passage of a nationally recognized, psychometrically valid certification examination for certification as determined by the Board of Pharmacy. The Board of Pharmacy may, by rule, set ratios of technicians to pharmacists greater than three to one for the functions specified in rule.

Subd. 2. **Waivers by board permitted.** A pharmacist in charge in a pharmacy may petition the board for authorization to allow a pharmacist to supervise more than three pharmacy technicians. The pharmacist's petition must include provisions addressing how patient care and safety will be maintained. A petition filed with the board under this subdivision shall be deemed approved 90 days after the board receives the petition, unless the board denies the petition within 90 days of receipt and notifies the petitioning pharmacist of the petition's denial and the board's reasons for denial.

Subd. 3. **Registration fee.** The board shall not register an individual as a pharmacy technician unless all applicable fees specified in section 151.065 have been paid.

History: *1997 c 132 s 3; 1999 c 63 s 1; 2000 c 276 s 1; 1Sp2011 c 9 art 5 s 20; 2015 c 71 art 10 s 33*

151.11 [Repealed, 1988 c 550 s 20]

151.12 RECIPROCITY; LICENSURE.

The board may in its discretion grant licensure without examination to any pharmacist licensed by the Board of Pharmacy or a similar board of another state which accords similar recognition to licensees of this state; provided, the requirements for licensure in such other state are in the opinion of the board equivalent to those herein provided. The fee for licensure shall be in the amount specified in section 151.065.

History: *(5808-12) 1937 c 354 s 12; 1961 c 394 s 4; 1973 c 639 s 5; 1976 c 222 s 87; 1Sp2011 c 9 art 5 s 21*

151.13 RENEWAL FEE; CONTINUING EDUCATION.

Subdivision 1. **Renewal fee.** Every person licensed by the board as a pharmacist shall pay to the board the annual renewal fee specified in section 151.065. The board may charge the late fee specified in section 151.065 if the renewal fee and application are not received by the board prior to the date specified by the board. It shall be unlawful for any person licensed as a pharmacist who refuses or fails to pay any applicable renewal or late fee to practice pharmacy in this state. Every certificate and license shall expire at the time therein prescribed.

Subd. 2. **Continuing education.** The board may appoint an advisory task force on continuing education, consisting of not more than ten members, to study continuing education programs and requirements and to submit its report and recommendations to the board. The task force shall expire, and the compensation and removal of members shall be as provided in section 15.059.

History: *(5808-13) 1937 c 354 s 13; 1961 c 394 s 5; 1969 c 486 s 1; 1973 c 655 s 1; 1976 c 222 s 88; 1983 c 260 s 38; 1990 c 412 s 3; 1Sp2011 c 9 art 5 s 22*

151.14 REINSTATEMENTS.

Any person who has been licensed by the board and has defaulted in the payment of the renewal fee may be reinstated within two years of such default without examination, upon payment of the arrears and upon compliance with the provisions of section 151.13, subdivision 2.

History: *(5808-14) 1937 c 354 s 14; 1973 c 655 s 2; 1976 c 222 s 89*

151.15 COMPOUNDING DRUGS UNLAWFUL UNDER CERTAIN CONDITIONS.

Subdivision 1. **Location.** It shall be unlawful for any person to compound, dispense, vend, or sell drugs, medicines, chemicals, or poisons in any place other than a pharmacy, except as provided in this chapter.

Subd. 2. **Proprietors of pharmacies.** No proprietor of a pharmacy shall permit the compounding or dispensing of prescriptions except by a pharmacist or by a pharmacist intern under the personal supervision of a pharmacist; or the vending or selling of drugs, medicines, chemicals, or poisons in the proprietor's pharmacy except under the personal supervision of a pharmacist.

Subd. 3. **Unlicensed persons; veterinary legend drugs.** It shall be unlawful for any person other than a licensed veterinarian or pharmacist to compound or dispense veterinary legend drugs except as provided in this chapter.

Subd. 4. **Unlicensed persons; legend drugs.** It shall be unlawful for any person other than a licensed practitioner or pharmacist to compound or dispense legend drugs except as provided in this chapter.

History: *(5808-16) 1937 c 354 s 16; 1967 c 377 s 3; 1986 c 444; 1988 c 550 s 10; 1990 c 526 s 4; 1991 c 213 s 2; 1994 c 632 art 2 s 37*

151.16 VIOLATION A GROSS MISDEMEANOR.

Every person who violates any of the provisions of section 151.15, when the death of a human being results from such violation shall be guilty of a gross misdemeanor. This section is supplementary to existing laws relating to homicide and not a repeal thereof.

History: *(5808-17) 1937 c 354 s 17*

151.17 UNLAWFUL USE OF "PHARMACIST."

It shall be unlawful for any person to falsely assume or pretend to the title of pharmacist.

History: *(5808-18) 1937 c 354 s 18*

151.18 UNLAWFUL TO USE MISLEADING NAME.

It is unlawful for any person to carry on, conduct, or transact a retail business under a name which contains as a part thereof the words "drugs," "drug store," "pharmacy," "medicine," "apothecary," or "chemist shop," or any abbreviation, translation, extension, or variation thereof; or in any manner by advertisement,

circular, or poster, sign or otherwise, describe or refer to the place of business conducted by such person by such term, abbreviation, translation, extension, or variation unless the place so conducted is a pharmacy.

History: *(5808-19) 1937 c 354 s 19*

151.19 REGISTRATION; FEES.

Subdivision 1. **Pharmacy licensure requirements.** (a) No person shall operate a pharmacy without first obtaining a license from the board and paying any applicable fee specified in section 151.065. The license shall be displayed in a conspicuous place in the pharmacy for which it is issued and expires on June 30 following the date of issue. It is unlawful for any person to operate a pharmacy unless the license has been issued to the person by the board.

(b) Application for a pharmacy license under this section shall be made in a manner specified by the board.

(c) No license shall be issued or renewed for a pharmacy located within the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal and state law and according to rules adopted by the board. No license shall be issued for a pharmacy located outside of the state unless the applicant agrees to operate the pharmacy in a manner prescribed by federal law and, when dispensing medications for residents of this state, the laws of this state, and Minnesota Rules.

(d) No license shall be issued or renewed for a pharmacy that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of such licensure or registration.

(e) The board shall require a separate license for each pharmacy located within the state and for each pharmacy located outside of the state at which any portion of the dispensing process occurs for drugs dispensed to residents of this state.

(f) The board shall not issue an initial or renewed license for a pharmacy unless the pharmacy passes an inspection conducted by an authorized representative of the board. In the case of a pharmacy located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

(g) The board shall not issue an initial or renewed license for a pharmacy located outside of the state unless the applicant discloses and certifies:

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

(2) 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;

(3) that it agrees to cooperate with, and provide information to, the board concerning matters related to dispensing drugs to residents of this state;

(4) that, during its regular hours of operation, but no 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

(5) that, upon request of a resident of a long-term care facility located in this state, 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 section 151.415, subdivision 5.

Subd. 2. [Repealed, 2013 c 108 art 10 s 13]

Subd. 3. **Sale of federally restricted medical gases.** (a) A person or establishment not licensed as a pharmacy or a practitioner shall not engage in the retail sale or distribution of federally restricted medical gases without first obtaining a registration from the board and paying the applicable fee specified in section 151.065. The registration shall be displayed in a conspicuous place in the business for which it is issued and expires on the date set by the board. It is unlawful for a person to sell or distribute federally restricted medical gases unless a certificate has been issued to that person by the board.

(b) Application for a medical gas distributor registration under this section shall be made in a manner specified by the board.

(c) No registration shall be issued or renewed for a medical gas distributor located within the state unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board. No license shall be issued for a medical gas distributor located outside of the state unless the applicant agrees to operate in a manner prescribed by federal law and, when distributing medical gases for residents of this state, the laws of this state and Minnesota Rules.

(d) No registration shall be issued or renewed for a medical gas distributor that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of the licensure or registration. The board may, by rule, establish standards for the registration of a medical gas distributor that is not required to be licensed or registered by the state in which it is physically located.

(e) The board shall require a separate registration for each medical gas distributor located within the state and for each facility located outside of the state from which medical gases are distributed to residents of this state.

(f) The board shall not issue an initial or renewed registration for a medical gas distributor unless the medical gas distributor passes an inspection conducted by an authorized representative of the board. In the case of a medical gas distributor located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Subd. 4. **Licensing of physicians to dispense drugs; renewals.** (a) The board may grant a license to any physician licensed under chapter 147 who provides services in a health care facility located in a designated health professional shortage area authorizing the physician to dispense drugs to individuals for whom pharmaceutical care is not reasonably available. The license may be renewed annually. Any physician licensed under this subdivision shall be limited to dispensing drugs in a limited service pharmacy and shall be governed by the rules adopted by the board when dispensing drugs.

(b) For the purposes of this subdivision, pharmaceutical care is not reasonably available if the limited service pharmacy in which the physician is dispensing drugs is located in a health professional shortage area, and no other licensed pharmacy is located within 15 miles of the limited service pharmacy.

(c) For the purposes of this subdivision, section 151.15, subdivision 2, shall not apply, and section 151.215 shall not apply provided that a physician granted a license under this subdivision certifies each filled prescription in accordance with Minnesota Rules, part 6800.3100, subpart 3.

(d) Notwithstanding section 151.102, a physician granted a license under this subdivision may be assisted by a pharmacy technician if the technician holds a valid certification from the Pharmacy Technician Certification Board or from another national certification body for pharmacy technicians that requires passage of a nationally recognized psychometrically valid certification examination for certification as determined by the board. The physician may supervise the pharmacy technician as long as the physician assumes responsibility for all functions performed by the technician. For purposes of this subdivision, supervision does not require the physician to be physically present if the physician or a licensed pharmacist is available, either electronically or by telephone.

(e) Nothing in this subdivision shall be construed to prohibit a physician from dispensing drugs pursuant to section 151.37 and Minnesota Rules, parts 6800.9950 to 6800.9954.

History: *(5808-20) 1937 c 354 s 20; 1953 c 76 s 3; 1961 c 394 s 6; 1969 c 486 s 2; 1976 c 222 s 90; 1986 c 444; 1988 c 550 s 11; 1989 c 314 s 1; 2007 c 147 art 11 s 4; 1Sp2011 c 9 art 5 s 23; 2012 c 166 s 3; 2013 c 108 art 10 s 2,3*

151.20 [Repealed, 1969 c 933 s 22]

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 a prescription drug order without the approval of the prescriber.

Subd. 2. **Dispense as written prescription drug orders.** When a pharmacist receives a paper or hard copy prescription drug order 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 for which the prescriber has expressly indicated that the prescription is to be dispensed as communicated, the pharmacist shall dispense the drug as prescribed.

Subd. 3. **Other prescription drug orders.** 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 or, if a biological product is prescribed, a less expensive interchangeable biological product, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generically equivalent drug or the interchangeable biological product, 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 unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist may not substitute a biological product unless the U.S. Food and Drug Administration has determined the substituted biological product to be interchangeable with the prescribed biological product. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug or biological product other than the specific drug or biological product 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.

Subd. 4. **Pricing.** A pharmacist dispensing a drug under the provisions of subdivision 3 shall not dispense a drug of a higher retail price than that of the drug prescribed. If more than one safely interchangeable drug is available in a pharmacist's stock, then the pharmacist shall dispense the least expensive alternative.

Subd. 4a. **Sign.** A pharmacy must post a sign in a conspicuous location and in a typeface easily seen at the counter where prescriptions are dispensed stating: "In order to save you money, this pharmacy will substitute whenever possible an FDA-approved, less expensive, generic drug product, which is therapeutically equivalent to and safely interchangeable with the one prescribed by your doctor, unless you object to this substitution."

Subd. 5. **Reimbursement.** Nothing in this section requires a pharmacist to substitute a drug if the substitution will make the transaction ineligible for third-party reimbursement.

Subd. 6. **Disclosure.** When a pharmacist dispenses a brand name legend drug and, at that time, a less expensive generically equivalent drug or interchangeable biological product is also available in the pharmacist's stock, the pharmacist shall disclose to the purchaser that a generically equivalent drug or interchangeable biological product is available.

Subd. 7. **Drug formulary.** This section does not apply when a pharmacist is dispensing a prescribed drug to persons covered under a managed health care plan that maintains a mandatory or closed drug formulary.

Subd. 8. **List of excluded products.** The Drug Formulary Committee established under section 256B.0625, subdivision 13, shall establish a list of drug products that are to be excluded from this section. This list shall be updated on an annual basis and shall be provided to the board for dissemination to pharmacists licensed in the state.

Subd. 9. **Extended supply.** (a) After a patient has obtained an initial 30-day supply of a prescription drug, and the patient returns to the pharmacy to obtain a refill, a pharmacist may dispense up to a 90-day supply of that prescription drug to the patient when the following requirements are met:

(1) the total quantity of dosage units dispensed by the pharmacist does not exceed the total quantity of dosage units of the remaining refills authorized by the prescriber; and

(2) the pharmacist is exercising the pharmacist's professional judgment.

(b) The initial 30-day supply requirement in paragraph (a) is not required if the prescription has previously been filled with a 90-day supply.

(c) Notwithstanding paragraph (a), a pharmacist may not exceed the number of dosage units authorized by a prescriber for an initial prescription or subsequent refills if:

(1) the prescriber has specified on the prescription that, due to medical necessity, the pharmacist may not exceed the number of dosage units identified on the prescription; or

(2) the prescription drug is a controlled substance, as defined in section 152.01, subdivision 4.

Subd. 10. **Electronic entry.** (a) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the name and manufacturer of the biological product dispensed.

(b) The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) an interoperable electronic medical records system;

(2) an electronic prescribing technology;

(3) a pharmacy benefit management system; or

(4) a pharmacy record.

(c) Entry into an electronic records system as described in paragraph (b) is presumed to provide notice to the prescriber.

(d) When electronic communication as specified in paragraph (b) is not possible, the pharmacist or the pharmacist's designee shall communicate to the prescriber the name and manufacturer of the biological product dispensed by using mail, facsimile, telephone, or other secure means of electronic transmission.

(e) Communication of the name and manufacturer of the biological product dispensed shall not be required if:

(1) there is no U.S. Food and Drug Administration-approved interchangeable biological product for the product prescribed; or

(2) a prescription is being refilled and the biological product being dispensed is the same product dispensed on the prior filling of the prescription.

History: *(5808-22) 1937 c 354 s 22; 1969 c 933 s 10; 1975 c 101 s 2; 1986 c 444; 1993 c 345 art 5 s 10; 1994 c 625 art 8 s 48,49; 1997 c 202 art 2 s 40; 2007 c 123 s 125-128; 2016 c 122 s 1; 2017 c 84 s 4*

151.211 RECORDS OF PRESCRIPTIONS.

Subdivision 1. **Retention of prescription drug orders.** All prescription drug orders shall be kept on file at the location from which dispensing of the ordered drug occurs for a period of at least two years. Prescription drug orders that are electronically prescribed must be kept on file in the format in which they were originally received. Written or printed prescription drug orders and verbal prescription drug orders reduced to writing, must be kept on file as received or transcribed, except that such orders may be kept in an electronic format as allowed by the board. Electronic systems used to process and store prescription drug orders must be compliant with the requirements of this chapter and the rules of the board. Prescription drug orders that are stored in an electronic format, as permitted by this subdivision, may be kept on file at a remote location provided that they are readily and securely accessible from the location at which dispensing of the ordered drug occurred.

Subd. 2. **Refill requirements.** A prescription drug order may be refilled only with the written, electronic, or verbal consent of the prescriber and in accordance with the requirements of this chapter, the rules of the

board, and where applicable, section 152.11. The date of such refill must be recorded and initialed upon the original prescription drug order, or within the electronically maintained record of the original prescription drug order, by the pharmacist, pharmacist intern, or practitioner who refills the prescription.

History: *1969 c 933 s 11; 1973 c 639 s 6; 1986 c 444; 1988 c 550 s 12; 2014 c 291 art 5 s 8*

151.212 LABEL OF PRESCRIPTION DRUG CONTAINERS.

Subdivision 1. **Prescription drugs.** Drugs dispensed pursuant to a prescription shall bear a label permanently affixed to the immediate container in which the drug is dispensed and which is received by the purchaser. The label shall bear the name of the manufacturer or distributor of the finished dosage form of the drug and all other information required by law and by rules of the board.

Subd. 2. **Controlled substances.** (a) In addition to the requirements of subdivision 1, when the use of any drug containing a controlled substance, as defined in chapter 152, or any other drug determined by the board, either alone or in conjunction with alcoholic beverages, may impair the ability of the user to operate a motor vehicle, the board shall require by rule that notice be prominently set forth on the label or container. Rules promulgated by the board shall specify exemptions from this requirement when there is evidence that the user will not operate a motor vehicle while using the drug.

(b) In addition to the requirements of subdivision 1, whenever a prescription drug containing an opiate is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug must prominently display on the label or container a notice that states "Caution: Opioid. Risk of overdose and addiction."

Subd. 3. **Veterinary drugs.** Drugs dispensed, sold, or distributed in any manner pursuant to the order of a licensed veterinarian shall bear a label permanently affixed to the container in which the drug is dispensed and which is received by the purchaser. The label shall bear the name of the manufacturer or distributor of the finished dosage form of the drug and all other information required by law and the rules of the board.

History: *1969 c 933 s 12; 1975 c 101 s 3; 1975 c 356 s 1; 1976 c 338 s 5; 1985 c 248 s 70; 1988 c 550 s 13,14; 1Sp2017 c 6 art 12 s 1*

151.213 COPIES OF PRESCRIPTIONS.

Prescriptions on file in a pharmacy are not a public record. A person having custody of or access to such prescription orders shall not divulge the contents thereof or provide a copy thereof to anyone except to:

(1) the patient for whom the prescription was issued, the patient's agent, or another pharmacist acting on behalf of the patient or the patient's agent;

(2) the licensed practitioner who issued the prescription;

(3) the licensed practitioner who is then treating the patient;

(4) a member, inspector, or investigator of the board or any federal, state, county, or municipal officer whose duty it is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug;

(5) an agency of government charged with the responsibility of providing medical care for the patient;

(6) an insurance carrier or attorney on receipt of written authorization signed by the patient or the patient's legal representative, authorizing the release of such information;

(7) any person duly authorized by a court order.

Such copies furnished shall bear on the face thereof the statement "Copy for information only," and may be filed to account for the dispensing of a drug only if such dispensing is authorized in writing or orally by the prescriber and communicated to the pharmacist dispensing and filing such copy.

History: *1969 c 933 s 13; 1986 c 444*

151.214 PAYMENT DISCLOSURE.

Subdivision 1. **Explanation of pharmacy benefits.** A pharmacist licensed under this chapter must provide to a patient, for each prescription dispensed where part or all of the cost of the prescription is being paid or reimbursed by an employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager, the patient's co-payment amount and the pharmacy's own usual and customary price of the prescription or the amount the pharmacy will be paid for the prescription drug by the patient's employer-sponsored plan or health plan company, or its contracted pharmacy benefit manager.

Subd. 2. **No prohibition on disclosure.** No contracting agreement between an employer-sponsored health plan or health plan company, or its contracted pharmacy benefit manager, and a resident or nonresident pharmacy registered under this chapter, may prohibit the pharmacy from disclosing to patients information a pharmacy is required or given the option to provide under subdivision 1.

History: *2004 c 268 s 13; 2004 c 288 art 3 s 5; 2005 c 10 art 1 s 82; 2006 c 267 art 1 s 6*

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*

151.22 LIABILITY FOR QUALITY OF DRUGS.

Every pharmacist in charge or proprietor of a pharmacy shall be responsible for the quality of all drugs, medicines, chemicals, and poisons procured for use and sold therein, except proprietary medicines or other articles sold in the original package of the manufacturer.

History: *(5808-23) 1937 c 354 s 23; 1969 c 933 s 14*

151.23 POISONS MUST BE LABELED.

It shall be unlawful for any person to sell at retail any poison without affixing to the package or receptacle containing the same a label conspicuously bearing the word "poison," and the name and the business address of the seller, and being satisfied that such poison is to be legitimately used. This section shall not apply to the sale of poison on a physician's written prescription or in the original package of the manufacturer.

History: *(5808-24) 1937 c 354 s 24; 1986 c 444*

151.24 SALE OF POISONS MUST BE RECORDED.

It shall be unlawful:

(1) for any person, either acting independently or while in the employ of another, to sell or give away any poison, as designated by the board, without first recording in a book to be kept for that purpose with an indelible pencil or ink the date, the name and address of the person to whom, and the amount and kind of poison, delivered, except when such poison is sold on the written prescription of a physician;

(2) to give a false name to be recorded;

(3) for any person having custody of any such record book to refuse to produce it on demand for the inspection of any authorized agent of the board or other duly authorized officer.

History: *(5808-25) 1937 c 354 s 25; 1986 c 444*

151.25 [Repealed, 2013 c 108 art 10 s 13]

151.252 LICENSING OF DRUG MANUFACTURERS; FEES; PROHIBITIONS.

Subdivision 1. **Requirements.** (a) No person shall act as a drug manufacturer without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(b) Application for a drug manufacturer license under this section shall be made in a manner specified by the board.

(c) No license shall be issued or renewed for a drug manufacturer unless the applicant agrees to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

(d) No license shall be issued or renewed for a drug manufacturer that is required to be registered pursuant to United States Code, title 21, section 360, unless the applicant supplies the board with proof of registration. The board may establish by rule the standards for licensure of drug manufacturers that are not required to be registered under United States Code, title 21, section 360.

(e) No license shall be issued or renewed for a drug manufacturer that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a drug manufacturer that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each facility located within the state at which drug manufacturing occurs and for each facility located outside of the state at which drugs that are shipped into the state are manufactured.

(g) The board shall not issue an initial or renewed license for a drug manufacturing facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of a drug manufacturing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Subd. 1a. **Outsourcing facility.** (a) No person shall act as an outsourcing facility without first obtaining a license from the board and paying any applicable manufacturer licensing fee specified in section 151.065.

(b) Application for an outsourcing facility license under this section shall be made in a manner specified by the board and may differ from the application required of other drug manufacturers.

(c) No license shall be issued or renewed for an outsourcing facility unless the applicant agrees to operate in a manner prescribed for outsourcing facilities by federal and state law and according to Minnesota Rules.

(d) No license shall be issued or renewed for an outsourcing facility unless the applicant supplies the board with proof of such registration by the United States Food and Drug Administration as required by United States Code, title 21, section 353b.

(e) No license shall be issued or renewed for an outsourcing facility that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of such licensure or registration. The board may establish, by rule, standards for the licensure of an outsourcing facility that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each outsourcing facility located within the state and for each outsourcing facility located outside of the state at which drugs that are shipped into the state are prepared.

(g) The board shall not issue an initial or renewed license for an outsourcing facility unless the facility passes an inspection conducted by an authorized representative of the board. In the case of an outsourcing facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located or by the United States Food and Drug Administration, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

Subd. 2. **Prohibition.** It is unlawful for any person engaged in drug manufacturing to sell legend drugs to anyone located in this state except as provided in this chapter.

Subd. 3. **Payment to practitioner; reporting.** Unless prohibited by United States Code, title 42, section 1320a-7h, a drug manufacturer shall file with the board an annual report, in a form and on the date prescribed by the board, identifying all payments, honoraria, reimbursement, or other compensation authorized under section 151.461, clauses (4) and (5), paid to practitioners in Minnesota during the preceding calendar year. The report shall identify the nature and value of any payments totaling $100 or more to a particular practitioner during the year, and shall identify the practitioner. Reports filed under this subdivision are public data.

History: *2013 c 108 art 10 s 4; 2014 c 291 art 5 s 10*

151.253 COMPOUNDING.

Subdivision 1. **Exemption from manufacturing licensure requirement.** Section 151.252 shall not apply to:

(1) a practitioner engaged in extemporaneous compounding, anticipatory compounding, or compounding not done pursuant to a prescription drug order when permitted by this chapter or the rules of the board; and

(2) a pharmacy in which a pharmacist is engaged in extemporaneous compounding, anticipatory compounding, or compounding not done pursuant to a prescription drug order when permitted by this chapter or the rules of the board.

Subd. 2. **Compounded drug.** A drug product may be compounded under this section if a pharmacist or practitioner:

(1) compounds the drug product using bulk drug substances, as defined in the federal regulations published in Code of Federal Regulations, title 21, section 207.3(a)(4):

(i) that:

(A) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(B) if such a monograph does not exist, are drug substances that are components of drugs approved for use in this country by the United States Food and Drug Administration; or

(C) if such a monograph does not exist and the drug substance is not a component of a drug approved for use in this country by the United States Food and Drug Administration, that appear on a list developed by the United States Food and Drug Administration through regulations issued by the secretary of the federal Department of Health and Human Services pursuant to section 503A of the Food, Drug and Cosmetic Act under paragraph (d);

(ii) that are manufactured by an establishment that is registered under section 360 of the federal Food, Drug and Cosmetic Act, including a foreign establishment that is registered under section 360(i) of that act; and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(2) compounds the drug product using ingredients, other than bulk drug substances, that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapters on pharmacy compounding;

(3) does not compound a drug product that appears on a list published by the secretary of the federal Department of Health and Human Services in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

(4) does not compound any drug products that are essentially copies of a commercially available drug product; and

(5) does not compound any drug product that has been identified pursuant to United States Code, title 21, section 353a, as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.

The term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, that produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

Subd. 3. **Exceptions.** This section shall not apply to:

(1) compounded positron emission tomography drugs as defined in section 151.01, subdivision 38; or

(2) radiopharmaceuticals.

History: *2014 c 291 art 5 s 9*

151.26 EXCEPTIONS.

Subdivision 1. **Generally.** Nothing in this chapter shall subject a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine, to inspection by the State Board of Pharmacy, nor prevent the person from administering drugs, medicines, chemicals, or poisons in the person's practice, nor prevent a duly licensed practitioner from furnishing to a patient properly packaged and labeled drugs, medicines, chemicals, or poisons as may be considered appropriate in the treatment of such patient; unless the person is engaged in the dispensing, sale, or distribution of drugs and the board provides reasonable notice of an inspection.

Except for the provisions of section 151.37, nothing in this chapter applies to or interferes with the dispensing, in its original package and at no charge to the patient, of a legend drug that was packaged by a manufacturer and provided to the dispenser for dispensing as a professional sample. Samples of a controlled substance shall only be dispensed when one of the approved indications for the controlled substance is a seizure disorder and when the sample is prepared and distributed pursuant to Code of Federal Regulations, title 21, part 203, subpart D.

Nothing in this chapter shall prevent the sale of drugs, medicines, chemicals, or poisons at wholesale to licensed physicians, dentists and veterinarians for use in their practice, nor to hospitals for use therein.

Nothing in this chapter shall prevent the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes, or in the arts, nor interfere with the sale of insecticides, as defined in Minnesota Statutes 1974, section 24.069, and nothing in this chapter shall prevent the sale of common household preparations and other drugs, chemicals, and poisons sold exclusively for use for nonmedicinal purposes; provided that this exception does not apply to any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and, when introduced into the body, induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

Nothing in this chapter shall apply to or interfere with the vending or retailing of any nonprescription medicine or drug not otherwise prohibited by statute that is prepackaged, fully prepared by the manufacturer or producer for use by the consumer, and labeled in accordance with the requirements of the state or federal Food and Drug Act; nor to the manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature, for use for nonmedicinal purposes; provided that this exception does not apply to any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and, when introduced into the body, induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption. Nothing in this chapter shall prevent the sale of drugs or medicines by licensed pharmacists at a discount to persons over 65 years of age.

Subd. 2. [Repealed, 1973 c 639 s 11]

History: *(5808-27) 1937 c 354 s 27; 1953 c 76 s 5; 1969 c 627 s 1; 1971 c 192 s 1; 1973 c 639 s 8; 1Sp1981 c 4 art 1 s 82; 1986 c 444; 1988 c 550 s 16; 2014 c 285 s 4; 2014 c 291 art 5 s 11*

151.27 EXPENSES.

The expenses of administering sections 151.01 to 151.40 shall be paid from the appropriations made to the State Board of Pharmacy.

History: *(5808-28) 1937 c 354 s 28; 1973 c 638 s 30; 1976 c 222 s 92*

151.28 [Repealed, 1988 c 550 s 20]

151.29 VIOLATION A MISDEMEANOR.

Any person violating any of the provisions of this chapter, or rules hereunder, shall be guilty of a misdemeanor, unless otherwise provided.

History: *(5808-30) 1937 c 354 s 30; 1985 c 248 s 70*

151.30 COUNTY ATTORNEY TO PROSECUTE.

It shall be the duty of the county attorney of the county wherein any offense under this chapter is committed to prosecute the offender, except that when offenses hereunder are committed in cities of the first class it shall be the duty of the city attorney thereof to prosecute the offender. Such prosecutor is authorized to examine the books of any manufacturer or wholesale dealer within the state for the purpose of acquiring information to aid in the prosecution.

History: *(5808-31) 1937 c 354 s 31*

151.301 REPORTS TO COMMISSIONER OF HEALTH.

(a) The board shall maintain a record of an event that comes to the board's attention that, in the judgment of the board or a committee of the board, qualifies as an adverse health care event under section 144.7065.

(b) Within 30 days of making a determination under paragraph (a) that an event qualifies as an adverse health care event, the board shall forward to the commissioner of health a report of the event, including the facility involved, the date of the event, and information known to the board regarding the event. The report shall not include any identifying information for any of the health care professionals, facility employees, or patients involved.

History: *2004 c 186 s 9*

151.302 IMMUNITY.

Members of the board and persons employed by the board or engaged in maintaining records and making reports regarding adverse health care events are immune from civil liability and criminal prosecution for any actions, transactions, or publications in the execution of or relating to their duties under section 151.301.

History: *2004 c 186 s 10*

151.31 [Repealed, 1988 c 550 s 20]

PHARMACY PRACTICE ACT OF 1988

151.32 CITATION.

The title of sections 151.01 to 151.40 shall be the Pharmacy Practice Act.

History: *(5808-35) 1937 c 354 s 35; 1988 c 550 s 17; 2017 c 40 art 1 s 40*

151.33 CARELESS DISTRIBUTION OF DRUGS.

Subdivision 1. **Prohibited.** No person, directly or indirectly, by agent or otherwise, shall scatter, distribute, or give away any samples of any medicine, drugs, or medical compounds, salve, or liniment of any kind unless the same is delivered into the hands of an adult person, or mailed to such persons through the regular mail service.

Subd. 2. **Penalty.** Any person violating any provision of this section shall be guilty of a misdemeanor.

History: *(10275, 10276) 1905 c 33 s 1,2; 1971 c 23 s 15*

151.34 PROHIBITED ACTS.

It shall be unlawful to:

(1) manufacture, sell or deliver, hold or offer for sale any drug that is adulterated or misbranded;

(2) adulterate or misbrand any drug;

(3) receive in commerce any drug that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise;

(4) refuse to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by this chapter;

(5) remove or dispose of a detained or embargoed article in violation of this chapter;

(6) alter, mutilate, destroy, obliterate, or remove the whole or any part of the labeling of, or to do any other act with respect to a drug, if such act is done while such drug is held for sale and results in such drug being adulterated or misbranded;

(7) use for a person's own advantage or to reveal other than to the board or its authorized representative or to the courts when required in any judicial proceeding under this chapter any information acquired under authority of this chapter concerning any method or process that is a trade secret and entitled to protection;

(8) use on the labeling of any drug any representation or suggestion that an application with respect to such drug is effective under the federal act or that such drug complies with such provisions;

(9) in the case of a manufacturer, packer, or distributor offering legend drugs for sale within this state, fail to maintain for transmittal or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter that is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under provisions of this chapter;

(10) conduct a pharmacy without a pharmacist in charge;

(11) dispense a legend drug without first obtaining a valid prescription for that drug;

(12) conduct a pharmacy without proper registration with the board;

(13) practice pharmacy without being licensed to do so by the board;

(14) sell at retail federally restricted medical gases without proper registration with the board except as provided in this chapter; or

(15) sell any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and, when introduced into the body, induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

History: *1969 c 933 s 15; 1971 c 25 s 35; 1988 c 550 s 18; 1989 c 314 s 2; 1990 c 412 s 4; 2014 c 285 s 5*

151.35 DRUGS, ADULTERATION.

A drug shall be deemed to be adulterated:

(1) if it consists in whole or in part of any filthy, putrid or decomposed substance; or if it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been rendered injurious to health, or whereby it may have been contaminated with filth; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice as required under the federal act to assure that such drug is safe and has the identity, strength, quality, and purity characteristics, which it purports or is represented to possess; or the facility in which it was produced was not registered by the United States Food and Drug Administration or licensed by the board; or, its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act, or it is a color additive, the intended use of which in or on drugs is for the purposes of coloring only, and is unsafe within the meaning of the federal act;

(2) if it purports to be or is represented as a drug the name of which is recognized in the United States Pharmacopoeia or the National Formulary, and its strength differs from, or its quality or purity falls below, the standard set forth therein. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in the United States Pharmacopoeia or the National Formulary shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(3) if it is not subject to the provisions of paragraph (2) of this section and its strength differs from, or its purity or quality differs from that which it purports or is represented to possess;

(4) if any substance has been mixed or packed therewith so as to reduce its quality or strength, or substituted wholly or in part therefor.

History: *1969 c 933 s 16; 2014 c 285 s 6*

151.36 DRUGS, MISBRANDING.

A drug shall be deemed to be misbranded:

(1) if its labeling is false or misleading in any particular;

(2) if in package form and not dispensed pursuant to a prescription unless it bears a label containing (a) the name and place of business of the manufacturer, packer, or distributor, (b) a statement of ingredients, and (c) an accurate statement of the net quantity of the contents in terms of weight, measure, or numerical count, provided, however, that under (c) reasonable variations shall be permitted, and exceptions as to small packages shall be allowed in accordance with the federal act;

(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it otherwise fails to meet the labeling requirements of the federal act.

History: *1969 c 933 s 17; 2014 c 285 s 7*

151.361 MANUFACTURER DISCLOSURE.

Subdivision 1. **After January 1, 1976.** The manufacturer, packager, or distributor of any human use legend drug sold, delivered, or offered for sale in the state of Minnesota after January 1, 1976 must have printed on the label on the immediate container of the drug the name and address of the manufacturer of the finished dosage form of the drug.

Subd. 2. **After January 1, 1983.** (a) No legend drug in solid oral dosage form may be manufactured, packaged or distributed for sale in this state after January 1, 1983 unless it is clearly marked or imprinted with a symbol, number, company name, words, letters, national drug code or other mark uniquely identifiable to that drug product. An identifying mark or imprint made as required by federal law or by the federal Food and Drug Administration shall be deemed to be in compliance with this section.

(b) The Board of Pharmacy may grant exemptions from the requirements of this section on its own initiative or upon application of a manufacturer, packager, or distributor indicating size or other characteristics that render the product impractical for the imprinting required by this section.

Subd. 3. **Penalty.** Failure to comply with the requirements of this section shall subject a drug to embargo in accordance with section 151.38.

History: *1975 c 101 s 4; 1981 c 206 s 1; 2014 c 291 art 5 s 12*

151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.

Subdivision 1. **Prohibition.** Except as otherwise provided in this chapter, it shall be unlawful for any person to have in possession, or to sell, give away, barter, exchange, or distribute a legend drug.

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 licensed dietitian or licensed nutritionist, pursuant to section 148.634; a nurse, pursuant to section 148.235, subdivisions 8 and 9; physician assistant; medical student or resident; or pharmacist according to section 151.01, subdivision 27, 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) The commissioner of health, if a licensed practitioner, or a person designated by the commissioner who is a licensed practitioner, may prescribe a legend drug to an individual or by protocol for mass dispensing purposes where the commissioner finds that the conditions triggering section 144.4197 or 144.4198, subdivision 2, paragraph (b), exist. The commissioner, if a licensed practitioner, or a designated licensed practitioner, may prescribe, dispense, or administer a legend drug or other substance listed in subdivision 10 to control tuberculosis and other communicable diseases. The commissioner may modify state drug labeling requirements, and medical screening criteria and documentation, where time is critical and limited labeling and screening are most likely to ensure legend drugs reach the maximum number of persons in a timely fashion so as to reduce morbidity and mortality.

(c) 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.

(d) A prescription drug order for the following drugs is not valid, unless it can be established that the prescription drug order was based on a documented patient evaluation, including an examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment:

(1) controlled substance drugs listed in section 152.02, subdivisions 3 to 5;

(2) drugs defined by the Board of Pharmacy as controlled substances under section 152.02, subdivisions 7, 8, and 12;

(3) muscle relaxants;

(4) centrally acting analgesics with opioid activity;

(5) drugs containing butalbital; or

(6) phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.

(e) For the purposes of paragraph (d), the requirement for an examination shall be met if an in-person examination has been completed in any of the following circumstances:

(1) the prescribing practitioner examines the patient at the time the prescription or drug order is issued;

(2) the prescribing practitioner has performed a prior examination of the patient;

(3) another prescribing practitioner practicing within the same group or clinic as the prescribing practitioner has examined the patient;

(4) a consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient; or

(5) the referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.

(f) Nothing in paragraph (d) or (e) prohibits a licensed practitioner from prescribing a drug through the use of a guideline or protocol pursuant to paragraph (a).

(g) Nothing in this chapter prohibits a licensed practitioner from issuing a prescription or dispensing a legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases guidance document issued by the United States Centers for Disease Control.

(h) Nothing in paragraph (d) or (e) limits prescription, administration, or dispensing of legend drugs through a public health clinic or other distribution mechanism approved by the commissioner of health or a community health board in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent.

(i) No pharmacist employed by, under contract to, or working for a pharmacy located within the state and licensed under section 151.19, subdivision 1, may dispense a legend drug based on a prescription that the pharmacist knows, or would reasonably be expected to know, is not valid under paragraph (d).

(j) No pharmacist employed by, under contract to, or working for a pharmacy located outside the state and licensed under section 151.19, subdivision 1, may dispense a legend drug to a resident of this state based on a prescription that the pharmacist knows, or would reasonably be expected to know, is not valid under paragraph (d).

(k) Nothing in this chapter prohibits the commissioner of health, if a licensed practitioner, or, if not a licensed practitioner, a designee of the commissioner who is a licensed practitioner, from prescribing legend drugs for field-delivered therapy in the treatment of a communicable disease according to the Centers For Disease Control and Prevention Partner Services Guidelines.

Subd. 2a. **Delegation.** A supervising physician may delegate to a physician assistant who is registered with the Board of Medical Practice and certified by the National Commission on Certification of Physician Assistants and who is under the supervising physician's supervision, the authority to prescribe, dispense, and administer legend drugs and medical devices, subject to the requirements in chapter 147A and other requirements established by the Board of Medical Practice in rules.

Subd. 3. **Veterinarians.** A licensed doctor of veterinary medicine, in the course of professional practice only and not for use by a human being, may personally prescribe, administer, and dispense a legend drug, and may cause the same to be administered or dispensed by an assistant under the doctor's direction and supervision.

Subd. 4. **Research.** (a) Any qualified person may use legend drugs in the course of a bona fide research project, but cannot administer or dispense such drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so.

(b) Drugs may be dispensed or distributed by a pharmacy licensed by the board for use by, or administration to, patients enrolled in a bona fide research study that is being conducted pursuant to either an investigational new drug application approved by the United States Food and Drug Administration or that has been approved by an institutional review board. For the purposes of this subdivision only:

(1) a prescription drug order is not required for a pharmacy to dispense a research drug, unless the study protocol requires the pharmacy to receive such an order;

(2) notwithstanding the prescription labeling requirements found in this chapter or the rules promulgated by the board, a research drug may be labeled as required by the study protocol;

(3) dispensing and distribution of research drugs by pharmacies shall not be considered manufacturing or wholesaling under this chapter; and

(4) a pharmacy may compound drugs for research studies as provided in this subdivision but must follow applicable standards established by United States Pharmacopeia, chapter 795 or 797, for nonsterile and sterile compounding, respectively.

(c) An entity that is under contract to a federal agency for the purpose of distributing drugs for bona fide research studies is exempt from the drug wholesaler licensing requirements of this chapter. Any other entity is exempt from the drug wholesaler licensing requirements of this chapter if the board finds that the entity is licensed or registered according to the laws of the state in which it is physically located and it is distributing drugs for use by, or administration to, patients enrolled in a bona fide research study that is being conducted pursuant to either an investigational new drug application approved by the United States Food and Drug Administration or that has been approved by an institutional review board.

Subd. 5. **Exclusion for course of practice.** Nothing in this chapter shall prohibit the sale to, or the possession of, a legend drug by licensed drug wholesalers, licensed manufacturers, registered pharmacies, local detoxification centers, licensed hospitals, bona fide hospitals wherein animals are treated, or licensed pharmacists and licensed practitioners while acting within the course of their practice only.

Subd. 6. **Exclusion for course of employment.** (a) Nothing in this chapter shall prohibit the possession of a legend drug by an employee, agent, or sales representative of a registered drug manufacturer, or an employee or agent of a registered drug wholesaler, or registered pharmacy, while acting in the course of employment.

(b) Nothing in this chapter shall prohibit an employee of the following entities, while acting in the course of employment, from possessing a legend drug for the purpose of disposing of the legend drug as pharmaceutical waste, provided that controlled substances listed in section 152.02, subdivisions 3 to 6, may only be collected and disposed of as allowed under section 152.105:

(1) a law enforcement agency;

(2) a hazardous waste transporter that has notified the Pollution Control Agency of its activity;

(3) a facility permitted by the Pollution Control Agency to treat, store, or dispose of hazardous waste, including household hazardous waste;

(4) a facility licensed by the Pollution Control Agency or a metropolitan county, as defined in section 473.121, as a very small quantity generator collection program or household hazardous waste collection program; or

(5) a sanitary district organized under chapter 115, or a special law.

Subd. 6a. **Collection of legend drugs by pharmacies.** A pharmacy licensed under section 151.19 may collect a legend drug from an ultimate user, or from a long-term care facility on behalf of an ultimate user who resides or resided at the long-term care facility, for the purpose of disposing of the legend drug as pharmaceutical waste, provided that:

(1) a pharmacy may collect and dispose of controlled substances listed in section 152.02, subdivisions 3 to 6, only as allowed under section 152.105; and

(2) a pharmacy that has established a controlled substance disposal program pursuant to section 152.105 may also collect and dispose of noncontrolled substance legend and nonlegend drugs, but only in the same manner in which it collects and disposes of controlled substances.

Subd. 7. **Exclusion for prescriptions.** (a) Nothing in this chapter shall prohibit the possession of a legend drug by a person for that person's use when it has been dispensed to the person in accordance with a valid prescription issued by a practitioner.

(b) Nothing in this chapter shall prohibit a person, for whom a legend drug has been dispensed in accordance with a written or oral prescription by a practitioner, from designating a family member, caregiver, or other individual to handle the legend drug for the purpose of assisting the person in obtaining or administering the drug or sending the drug for destruction.

(c) Nothing in this chapter shall prohibit a person for whom a legend drug has been dispensed in accordance with a valid prescription issued by a practitioner from transferring the legend drug to an entity identified in subdivision 6. Controlled substances listed in section 152.02, subdivisions 3 to 6, may only be collected, stored, transported, and disposed of as allowed under section 152.105.

Subd. 8. **Misrepresentation.** It is unlawful for a person to procure, attempt to procure, possess, or control a legend drug by any of the following means:

(1) deceit, misrepresentation, or subterfuge;

(2) using a false name; or

(3) falsely assuming the title of, or falsely representing a person to be a manufacturer, wholesaler, pharmacist, practitioner, or other authorized person for the purpose of obtaining a legend drug.

Subd. 9. **Exclusion for course of laboratory employment.** Nothing in this chapter shall prohibit the possession of a legend drug by an employee or agent of a registered analytical laboratory while acting in the course of laboratory employment.

Subd. 10. **Purchase of drugs and other agents by commissioner of health.** The commissioner of health, in preparation for and in carrying out the duties of sections 144.05, 144.4197, and 144.4198, may purchase, store, and distribute antituberculosis drugs, biologics, vaccines, antitoxins, serums, immunizing agents, antibiotics, antivirals, antidotes, other pharmaceutical agents, and medical supplies to treat and prevent communicable disease.

Subd. 10a. **Emergency use authorizations.** Nothing in this chapter shall prohibit the purchase, possession, or use of a legend drug by an entity acting according to an emergency use authorization issued by the United States Food and Drug Administration pursuant to United States Code, title 21, section 360bbb-3. The entity must be specifically tasked in a public health response plan to perform critical functions necessary to support the response to a public health incident or event.

Subd. 11. **Exclusion for health care educational programs.** Nothing in this section shall prohibit an accredited public or private postsecondary school from possessing a legend drug that is not a controlled substance listed in section 152.02, provided that:

(1) the school is approved by the United States Secretary of Education in accordance with requirements of the Higher Education Act of 1965, as amended;

(2) the school provides a course of instruction that prepares individuals for employment in a health care occupation or profession;

(3) the school may only possess those drugs necessary for the instruction of such individuals; and

(4) the drugs may only be used in the course of providing such instruction and are labeled by the purchaser to indicate that they are not to be administered to patients.

Those areas of the school in which legend drugs are stored are subject to section 151.06, subdivision 1, paragraph (a), clause (4).

Subd. 12. **Administration of opiate antagonists for drug overdose.** (a) A licensed physician, a licensed advanced practice registered nurse authorized to prescribe drugs pursuant to section 148.235, or a licensed physician assistant authorized to prescribe drugs pursuant to section 147A.18 may authorize the following individuals to administer opiate antagonists, as defined in section 604A.04, subdivision 1:

(1) an emergency medical responder registered pursuant to section 144E.27;

(2) a peace officer as defined in section 626.84, subdivision 1, paragraphs (c) and (d); and

(3) staff of community-based health disease prevention or social service programs.

(b) For the purposes of this subdivision, opiate antagonists may be administered by one of these individuals only if:

(1) the licensed physician, licensed physician assistant, or licensed advanced practice registered nurse has issued a standing order to, or entered into a protocol with, the individual; and

(2) the individual has training in the recognition of signs of opiate overdose and the use of opiate antagonists as part of the emergency response to opiate overdose.

(c) Nothing in this section prohibits the possession and administration of naloxone pursuant to section 604A.04.

Subd. 13. **Opiate antagonists protocol.** (a) The board shall develop an opiate antagonist protocol. When developing the protocol, the board shall consult with the Board of Medical Practice, the Board of Nursing, the commissioner of health, and professional associations of pharmacists, physicians, physician assistants, and advanced practice registered nurses.

(b) The commissioner of health shall provide the following items to medical consultants appointed under section 145A.04, subdivision 2a:

(1) educational materials concerning the need for, and opportunities to provide, greater access to opiate antagonists;

(2) the opiate antagonist protocol developed by the board under paragraph (a); and

(3) a notice of the liability protections under section 604A.04, subdivision 3, that are extended to cover the use of the opiate antagonist protocol developed under this subdivision.

(c) The commissioner of health may designate a practitioner who is authorized to prescribe opiate antagonists to enter into the written protocol developed under paragraph (a) with pharmacists practicing within one or more community health service areas, upon the request of the applicable community health board. A community health board making a request to the commissioner under this section must do so by October 1 for the subsequent calendar year.

(d) The immunity in section 604A.04, subdivision 3, is extended to both the commissioner of health and to the designated practitioner when prescribing according to the protocol under this subdivision. The commissioner of health and the designated practitioner are both deemed to be acting within the scope of employment for purposes of section 3.736, subdivision 9, when prescribing according to the protocol under this subdivision.

History: *1969 c 933 s 18; 1973 c 639 s 9; 1974 c 369 s 1; 1976 c 222 s 93,94; 1976 c 338 s 6; 1986 c 444; 1988 c 440 s 2; 1988 c 550 s 19; 1990 c 489 s 1; 1990 c 524 s 2; 1991 c 30 s 11; 1991 c 106 s 6; 1993 c 121 s 11; 1994 c 389 s 4,5; 1995 c 69 s 2; 1995 c 205 art 2 s 6; 1996 c 305 art 1 s 43; 2002 c 362 s 4; 2003 c 62 s 7; 2007 c 103 s 3; 2007 c 147 art 12 s 7; 2008 c 321 s 4,5; 2009 c 41 s 8,9; 2009 c 161 s 1; 2010 c 223 s 1,2; 2013 c 43 s 30; 2013 c 55 s 2; 2013 c 108 art 10 s 5; 2014 c 232 s 2; 2014 c 291 art 4 s 58; art 5 s 13; 2015 c 21 art 1 s 109; 2016 c 124 s 3-7*

151.375 INVESTIGATIONAL DRUG USE.

Subdivision 1. **Title; citation.** This section may be cited as the "Right to Try Act."

Subd. 2. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given them.

(b) "Eligible patient" means a patient who meets the requirements in subdivision 3.

(c) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase 1 of a clinical trial, but has not been approved for general use by the federal Food and Drug Administration (FDA), and is currently under investigation in a FDA clinical trial.

(d) "Terminal illness" means a condition or illness which, to a reasonable degree of medical probability, is not considered reversible and even with the administration of current FDA-approved and available treatments and the administration of life-sustaining procedures will soon result in death.

Subd. 3. **Eligibility.** In order for a patient to access an investigational drug, biological product, or device under this section, a physician must document in writing that the patient:

(1) has a terminal illness;

(2) has, in consultation with a physician, considered all other treatment options currently approved by the FDA;

(3) has been given a prescription or recommendation by a physician for an investigational drug, biological product, or device; and

(4) has given informed consent, in writing, for the use of the investigational drug, biological product, or device, or if the patient is under the age of 18, or lacks the mental capacity to provide informed consent, a parent or legal guardian has given informed consent, in writing, on behalf of the patient.

Subd. 4. **Availability.** (a) A manufacturer of an investigational drug, biological product, or device has the option of making its investigational drug, biological product, or device available to eligible patients under this section.

(b) Nothing in this section shall be construed to require a manufacturer to make an investigational drug, biological product, or device available.

Subd. 5. **Costs.** (a) A manufacturer may provide an investigational drug, biological product, or device without receiving compensation.

(b) A manufacturer may require an eligible patient to pay the costs associated with manufacturing the investigational drug, biological product, or device.

Subd. 6. **Professional licensing.** No health care provider shall be subject to a civil penalty or disciplinary action by any business, occupational, or professional licensing board, solely for providing a prescription or recommendation, or providing treatment to an eligible patient in accordance with this section. Nothing in this section affects a professional licensing board from taking action in response to violations of any other section of law.

Subd. 7. **Coverage.** Nothing in this section shall be construed to require that the costs associated with an investigational drug, biological product, or device be covered under private health coverage, a state public health care program, the state employee group insurance program, or a program administered by a state or local government agency that provides health care services to inmates residing in a state or county correctional facility.

Subd. 8. **Liability.** Nothing in this section shall create a separate private cause of action against any health care provider or entity involved in the care of an eligible patient using an investigational drug, biological product, or device, for any harm done to the patient resulting from the investigational drug, biological product, or device, so long as the health care provider or entity is complying with the requirements of this section.

Subd. 9. **Exception.** This section does not apply to a person committed to the custody of the commissioner of corrections unless the department's medical director approves the investigational drug, biological product, or device.

Subd. 10. **Severability.** If any provision of this section or its application to any person or circumstances is held to be invalid, the invalidity of the provision shall not affect any other provision of this section. The provisions of this section are severable.

History: *2015 c 15 s 1*

151.38 EMBARGOES.

(1) Whenever a duly authorized agent of the board finds or has probable cause to believe that any drug or medicine is adulterated, or so misbranded as to be dangerous or fraudulent, or is being sold, delivered, or offered for sale in violation of section 151.361, the agent shall affix thereto an appropriate marking, giving

notice that the article is, or is suspected of being, adulterated, misbranded or sold, delivered, or offered for sale in violation of section 151.361 and has been embargoed, and warning that it is unlawful for any person to remove or dispose of the embargoed article by sale or otherwise without permission from the agent or the court.

(2) When an embargoed article has been found by the agent to be adulterated or misbranded, or is being sold, delivered, or offered for sale in violation of section 151.361, the board shall, within 30 days, petition the district court in whose jurisdiction the article is embargoed for an order of condemnation. When an embargoed article is not so found by the agent, the agent shall remove the marking.

(3) If the court finds that an embargoed article is adulterated or misbranded, or is being sold, delivered, or offered for sale in violation of section 151.361, the article shall be destroyed at the expense of the claimant thereof, who shall also pay all court costs and fees, storage and other proper expenses. If the adulteration or misbranding, or lack of manufacturer disclosure as required by section 151.361 can be corrected by proper labeling or processing of the article, or by filing the proper documents with the court, the court, after the costs, fees, and expenses have been paid and a sufficient bond has been executed, may order that the article be delivered to the claimant for labeling, processing or filing under supervision of an agent of the board. The expense of the supervision shall be paid by claimant. The bond shall be returned to the claimant on the representation to the court by the board that the article is no longer in violation of this chapter and that the expenses of supervision have been paid.

History: *1969 c 933 s 19; 1975 c 101 s 5; 1986 c 444*

151.39 DISTRESSED DRUGS.

Subdivision 1. **Definition.** Distressed drugs shall mean drugs or medicines which have been subjected to accident, fire, flood, adverse temperatures, or other physical influences which could affect the potency, quality, purity, or efficacy of such drug or medicine could otherwise cause the drug or medicine to be adulterated or misbranded within the meaning of the provisions of this chapter.

Subd. 2. **Prohibition.** No person shall sell, barter, vend, give away, or exchange distressed drugs until the board has determined that such drugs are not adulterated or misbranded within the meaning of this chapter.

Subd. 3. **Notification.** Every person who owns or controls distressed drugs shall immediately notify the board of the existence of such drugs and the location thereof and the board shall promptly cause an inspection and examination to be made of such drugs.

Subd. 3a. **Importation.** No person may import distressed drugs into this state without notification to the board of the source, destination, kind and quantity of such drugs. Such drugs may not be sold or offered for sale without written approval of the board. The board shall grant such approval when the applicant has clearly demonstrated that such distressed drugs were inspected on the site within a reasonable period after the occurrence set forth in subdivision 1 by an agency of the foreign state satisfactory to the board and the furnishing of a written certification by such agency in such form as is satisfactory to the board indicating that there is no reasonable cause to believe the drugs are not adulterated or misbranded. Nothing herein shall be construed to prevent the board from exerting its authority and rights set forth in section 151.38 after such drugs have entered this state.

Subd. 4. **Board certification.** The board shall, within 30 days of such notification, indicate whether or not it has probable cause to believe that such drugs are adulterated or misbranded within the meaning of this chapter. If the board determines that no such probable cause exists, it shall furnish the owner or person

having control of such drugs a written certificate to that effect. If the board has probable cause to believe that the drugs are adulterated or misbranded, it shall follow the procedure set forth in section 151.38.

History: *1969 c 933 s 20; 1971 c 24 s 14; 1973 c 639 s 10; 1986 c 444*

151.40 POSSESSION AND SALE OF HYPODERMIC SYRINGES AND NEEDLES.

Subdivision 1. **Generally.** Except as otherwise provided in subdivision 2, it is unlawful for any person to possess, control, manufacture, sell, furnish, dispense, or otherwise dispose of hypodermic syringes or needles or any instrument or implement which can be adapted for subcutaneous injections, except by the following persons when acting in the course of their practice or employment: licensed practitioners, registered pharmacies and their employees or agents, licensed pharmacists, licensed doctors of veterinary medicine or their assistants, registered nurses, registered medical technologists, medical interns, licensed drug wholesalers, their employees or agents, licensed hospitals, licensed nursing homes, bona fide hospitals where animals are treated, licensed morticians, syringe and needle manufacturers, their dealers and agents, persons engaged in animal husbandry, clinical laboratories, persons engaged in bona fide research or education or industrial use of hypodermic syringes and needles provided such persons cannot use hypodermic syringes and needles for the administration of drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so, persons who administer drugs pursuant to an order or direction of a licensed doctor of medicine or of a licensed doctor of osteopathic medicine duly licensed to practice medicine.

Subd. 2. **Sales of limited quantities of clean needles and syringes.** (a) A registered pharmacy or its agent or a licensed pharmacist may sell, without a prescription, unused hypodermic needles and syringes in quantities of ten or fewer, provided the pharmacy or pharmacist complies with all of the requirements of this subdivision.

(b) At any location where hypodermic needles and syringes are kept for retail sale under this subdivision, the needles and syringes shall be stored in a manner that makes them available only to authorized personnel and not openly available to customers.

(c) No registered pharmacy or licensed pharmacist may advertise to the public the availability for retail sale, without a prescription, of hypodermic needles or syringes in quantities of ten or fewer.

(d) A registered pharmacy or licensed pharmacist that sells hypodermic needles or syringes under this subdivision may give the purchaser the materials developed by the commissioner of health under section 325F.785.

(e) A registered pharmacy or licensed pharmacist that sells hypodermic needles or syringes must certify to the commissioner of health participation in an activity, including but not limited to those developed under section 325F.785, that supports proper disposal of used hypodermic needles or syringes.

History: *1969 c 933 s 21; 1976 c 222 s 95; 1986 c 444; 1997 c 203 art 2 s 17; 2016 c 119 s 7*

151.41 [Repealed, 1981 c 323 s 4; 1983 c 312 art 1 s 27]

LONG-TERM CARE RESIDENT ACCESS TO PHARMACEUTICALS ACT

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*

WHOLESALE DRUG DISTRIBUTION LICENSING ACT

151.42 CITATION.

Sections 151.42 to 151.51 may be cited as the "Wholesale Drug Distribution Licensing Act of 1990."

History: *1990 c 568 art 2 s 20*

151.43 SCOPE.

Sections 151.42 to 151.51 apply to any person, partnership, corporation, or business firm engaging in the wholesale distribution of prescription drugs within the state.

History: *1990 c 526 s 6; 1990 c 568 art 2 s 21*

151.44 DEFINITIONS.

As used in sections 151.43 to 151.51, the following terms have the meanings given in paragraphs (a) to (h):

(a) "Wholesale drug distribution" means distribution of prescription or nonprescription drugs to persons other than a consumer or patient or reverse distribution of such drugs, but does not include:

(1) a sale between a division, subsidiary, parent, affiliated, or related company under the common ownership and control of a corporate entity;

(2) the purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for its own use from the organization or from other hospitals or health care entities that are members of such organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended through December 31, 1988, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) the sale, purchase, or trade of a drug or offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) the transfer of prescription or nonprescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(8) the distribution of prescription or nonprescription drug samples by manufacturers representatives; or

(9) the sale, purchase, or trade of blood and blood components.

(b) "Wholesale drug distributor" means anyone engaged in wholesale drug distribution including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution. A wholesale

drug distributor does not include a common carrier or individual hired primarily to transport prescription or nonprescription drugs.

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

(d) "Prescription drug" means a drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to United States Code, title 21, sections 811 and 812.

(e) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(f) "Blood components" means that part of blood separated by physical or mechanical means.

(g) "Reverse distribution" means the receipt of prescription or nonprescription drugs received from or shipped to Minnesota locations for the purpose of returning the drugs to their producers or distributors.

(h) "Reverse distributor" means a person engaged in the reverse distribution of drugs.

History: *1990 c 526 s 7; 1990 c 568 art 2 s 22; 2010 c 223 s 3; 2014 c 291 art 5 s 14*

151.45 [Repealed, 2013 c 108 art 10 s 13]

151.46 PROHIBITED DRUG PURCHASES OR RECEIPT.

It is unlawful for any person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under the laws of the state, except where otherwise provided. Licensed wholesale drug distributors other than pharmacies shall not dispense or distribute prescription drugs directly to patients. A person violating the provisions of this section is guilty of a misdemeanor.

History: *1990 c 526 s 9; 1990 c 568 art 2 s 24*

151.461 GIFTS TO PRACTITIONERS PROHIBITED.

It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, "gift" does not include:

(1) professional samples of a drug provided to a prescriber for free distribution to patients;

(2) items with a total combined retail value, in any calendar year, of not more than $50;

(3) a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;

(4) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;

(5) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;

(6) publications and educational materials; or

(7) salaries or other benefits paid to employees.

History: *1993 c 345 art 5 s 11*

151.47 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS.

Subdivision 1. **Requirements.** (a) All wholesale drug distributors are subject to the requirements of this subdivision.

(b) No person or distribution outlet shall act as a wholesale drug distributor without first obtaining a license from the board and paying any applicable fee specified in section 151.065.

(c) Application for a wholesale drug distributor license under this section shall be made in a manner specified by the board.

(d) No license shall be issued or renewed for a wholesale drug distributor to operate unless the applicant agrees to operate in a manner prescribed by federal and state law and according to the rules adopted by the board.

(e) No license may be issued or renewed for a drug wholesale distributor that is required to be licensed or registered by the state in which it is physically located unless the applicant supplies the board with proof of licensure or registration. The board may establish, by rule, standards for the licensure of a drug wholesale distributor that is not required to be licensed or registered by the state in which it is physically located.

(f) The board shall require a separate license for each drug wholesale distributor facility located within the state and for each drug wholesale distributor facility located outside of the state from which drugs are shipped into the state or to which drugs are reverse distributed.

(g) The board shall not issue an initial or renewed license for a drug wholesale distributor facility unless the facility passes an inspection conducted by an authorized representative of the board, or is accredited by an accreditation program approved by the board. In the case of a drug wholesale distributor facility located outside of the state, the board may require the applicant to pay the cost of the inspection, in addition to the license fee in section 151.065, unless the applicant furnishes the board with a report, issued by the appropriate regulatory agency of the state in which the facility is located, of an inspection that has occurred within the 24 months immediately preceding receipt of the license application by the board, or furnishes the board with proof of current accreditation. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in an inspection report have been corrected.

(h) As a condition for receiving and retaining a wholesale drug distributor license issued under sections 151.42 to 151.51, an applicant shall satisfy the board that it has and will continuously maintain:

(1) adequate storage conditions and facilities;

(2) minimum liability and other insurance as may be required under any applicable federal or state law;

(3) a viable security system that includes an after hours central alarm, or comparable entry detection capability; restricted access to the premises; comprehensive employment applicant screening; and safeguards against all forms of employee theft;

(4) a system of records describing all wholesale drug distributor activities set forth in section 151.44 for at least the most recent two-year period, which shall be reasonably accessible as defined by board regulations in any inspection authorized by the board;

(5) principals and persons, including officers, directors, primary shareholders, and key management executives, who must at all times demonstrate and maintain their capability of conducting business in conformity with sound financial practices as well as state and federal law;

(6) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, about each wholesale drug distributor to be licensed, including all pertinent corporate licensee information, if applicable, or other ownership, principal, key personnel, and facilities information found to be necessary by the board;

(7) written policies and procedures that assure reasonable wholesale drug distributor preparation for, protection against, and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods, and product recalls;

(8) sufficient inspection procedures for all incoming and outgoing product shipments; and

(9) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(i) An agent or employee of any licensed wholesale drug distributor need not seek licensure under this section.

Subd. 2. [Repealed, 2013 c 108 art 10 s 13]

Subd. 3. **Prohibition.** It is unlawful for any person engaged in wholesale drug distribution to sell drugs to a person located within the state or to receive drugs in reverse distribution from a person located within the state except as provided in this chapter.

History: *1990 c 526 s 10; 1990 c 568 art 2 s 25; 1993 c 345 art 5 s 12; 1Sp2011 c 9 art 5 s 25; 2013 c 108 art 10 s 6,7*

151.48 [Repealed, 2013 c 108 art 10 s 13]

151.49 LICENSE RENEWAL APPLICATION PROCEDURES.

Application blanks or notices for renewal of a license required by sections 151.42 to 151.51 shall be mailed or otherwise provided to each licensee on or before the first day of the month prior to the month in which the license expires and, if application for renewal of the license with the required fee and supporting documents is not made before the expiration date, the existing license or renewal shall lapse and become null and void upon the date of expiration.

History: *1990 c 526 s 12; 1990 c 568 art 2 s 27; 2013 c 108 art 10 s 8*

151.50 RULES.

The board shall adopt rules to carry out the purposes and enforce the provisions of sections 151.42 to 151.51. All rules adopted under this section shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration; and in case of conflict between a rule adopted by the board and a Food and Drug Administration wholesale drug distributor guideline, the latter shall control.

History: *1990 c 526 s 13; 1990 c 568 art 2 s 28*

151.51 BOARD ACCESS TO WHOLESALE DRUG DISTRIBUTOR RECORDS.

Wholesale drug distributors may keep records at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which they were shipped, provided that the records shall be made available for inspection within two working days of a request by the board. The records may be kept in any form permissible under federal law applicable to prescription drugs record keeping.

History: *1990 c 526 s 14; 1990 c 568 art 2 s 29*

CANCER DRUG REPOSITORY PROGRAM

151.55 CANCER DRUG REPOSITORY PROGRAM.

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

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

(c) "Cancer drug" means a prescription drug that is used to treat:

(1) cancer or the side effects of cancer; or

(2) the side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(d) "Cancer drug repository" means a medical facility or pharmacy that has notified the board of its election to participate in the cancer drug repository program.

(e) "Cancer supply" or "supplies" means prescription and nonprescription cancer supplies needed to administer a cancer drug.

(f) "Dispense" has the meaning given in section 151.01, subdivision 30.

(g) "Distribute" means to deliver, other than by administering or dispensing.

(h) "Donor" means an individual and not a drug manufacturer or wholesale drug distributor who donates a cancer drug or supply according to the requirements of the cancer drug repository program.

(i) "Medical facility" means an institution defined in section 144.50, subdivision 2.

(j) "Medical supplies" means any prescription and nonprescription medical supply needed to administer a cancer drug.

(k) "Pharmacist" has the meaning given in section 151.01, subdivision 3.

(l) "Pharmacy" means any pharmacy registered with the Board of Pharmacy according to section 151.19, subdivision 1.

(m) "Practitioner" has the meaning given in section 151.01, subdivision 23.

(n) "Prescription drug" means a legend drug as defined in section 151.01, subdivision 17.

(o) "Side effects of cancer" means symptoms of cancer.

(p) "Single-unit-dose packaging" means a single-unit container for articles intended for administration as a single dose, direct from the container.

(q) "Tamper-evident unit dose packaging" means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.

Subd. 2. **Establishment.** The Board of Pharmacy shall establish and maintain a cancer drug repository program, under which any person may donate a cancer drug or supply for use by an individual who meets the eligibility criteria specified under subdivision 4. Under the program, donations may be made on the premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements specified under subdivision 3.

Subd. 3. **Requirements for participation by pharmacies and medical facilities.** (a) To be eligible for participation in the cancer drug repository program, a pharmacy or medical facility must be licensed and in compliance with all applicable federal and state laws and administrative rules.

(b) Participation in the cancer drug repository program is voluntary. A pharmacy or medical facility may elect to participate in the cancer drug repository program by submitting the following information to the board, in a form provided by the board:

(1) the name, street address, and telephone number of the pharmacy or medical facility;

(2) the name and telephone number of a pharmacist who is employed by or under contract with the pharmacy or medical facility, or other contact person who is familiar with the pharmacy's or medical facility's participation in the cancer drug repository program; and

(3) a statement indicating that the pharmacy or medical facility meets the eligibility requirements under paragraph (a) and the chosen level of participation under paragraph (c).

(c) A pharmacy or medical facility may fully participate in the cancer drug repository program by accepting, storing, and dispensing or administering donated drugs and supplies, or may limit its participation to only accepting and storing donated drugs and supplies. If a pharmacy or facility chooses to limit its participation, the pharmacy or facility shall distribute any donated drugs to a fully participating cancer drug repository according to subdivision 8.

(d) A pharmacy or medical facility may withdraw from participation in the cancer drug repository program at any time upon notification to the board. A notice to withdraw from participation may be given by telephone or regular mail.

Subd. 4. **Individual eligibility requirements.** Any Minnesota resident who is diagnosed with cancer is eligible to receive drugs or supplies under the cancer drug repository program. Drugs and supplies shall be dispensed or administered according to the priority given under subdivision 6, paragraph (d).

Subd. 5. **Donations of cancer drugs and supplies.** (a) Any one of the following persons may donate legally obtained cancer drugs or supplies to a cancer drug repository, if the drugs or supplies meet the requirements under paragraph (b) or (c) as determined by a pharmacist who is employed by or under contract with a cancer drug repository:

(1) an individual who is 18 years old or older; or

(2) a pharmacy, medical facility, drug manufacturer, or wholesale drug distributor, if the donated drugs have not been previously dispensed.

(b) A cancer drug is eligible for donation under the cancer drug repository program only if the following requirements are met:

(1) the donation is accompanied by a cancer drug repository donor form described under paragraph (d) that is signed by the person making the donation or that person's authorized representative;

(2) the drug's expiration date is at least six months later than the date that the drug was donated;

(3) the drug is in its original, unopened, tamper-evident unit dose packaging that includes the drug's lot number and expiration date. Single-unit dose drugs may be accepted if the single-unit-dose packaging is unopened; and

(4) the drug is not adulterated or misbranded.

(c) Cancer supplies are eligible for donation under the cancer drug repository program only if the following requirements are met:

(1) the supplies are not adulterated or misbranded;

(2) the supplies are in their original, unopened, sealed packaging; and

(3) the donation is accompanied by a cancer drug repository donor form described under paragraph (d) that is signed by the person making the donation or that person's authorized representative.

(d) The cancer drug repository donor form must be provided by the board and shall state that to the best of the donor's knowledge the donated drug or supply has been properly stored and that the drug or supply has never been opened, used, tampered with, adulterated, or misbranded. The board shall make the cancer drug repository donor form available on the Board of Pharmacy's Web site.

(e) Controlled substances and drugs and supplies that do not meet the criteria under this subdivision are not eligible for donation or acceptance under the cancer drug repository program.

(f) Drugs and supplies may be donated on the premises of a cancer drug repository to a pharmacist designated by the repository. A drop box may not be used to deliver or accept donations.

(g) Cancer drugs and supplies donated under the cancer drug repository program must be stored in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with nondonated inventory.

Subd. 6. **Dispensing requirements.** (a) Drugs and supplies must be dispensed by a licensed pharmacist pursuant to a prescription by a practitioner or may be dispensed or administered by a practitioner according to the requirements of chapter 151 and within the practitioner's scope of practice.

(b) Cancer drugs and supplies shall be visually inspected by the pharmacist or practitioner before being dispensed or administered for adulteration, misbranding, and date of expiration. Drugs or supplies that have expired or appear upon visual inspection to be adulterated, misbranded, or tampered with in any way may not be dispensed or administered.

(c) Before a cancer drug or supply may be dispensed or administered to an individual, the individual must sign a cancer drug repository recipient form provided by the board acknowledging that the individual understands the information stated on the form. The form shall include the following information:

(1) that the drug or supply being dispensed or administered has been donated and may have been previously dispensed;

(2) that a visual inspection has been conducted by the pharmacist or practitioner to ensure that the drug has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging; and

(3) that the dispensing pharmacist, the dispensing or administering practitioner, the cancer drug repository, the Board of Pharmacy, and any other participant of the cancer drug repository program cannot guarantee the safety of the drug or supply being dispensed or administered and that the pharmacist or practitioner has determined that the drug or supply is safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or supply and the visual inspection required to be performed by the pharmacist or practitioner before dispensing or administering.

The board shall make the cancer drug repository form available on the Board of Pharmacy's Web site.

(d) Drugs and supplies shall only be dispensed or administered to individuals who meet the eligibility requirements in subdivision 4 and in the following order of priority:

(1) individuals who are uninsured;

(2) individuals who are enrolled in medical assistance, MinnesotaCare, Medicare, or other public assistance health care; and

(3) all other individuals who are otherwise eligible under subdivision 4 to receive drugs or supplies from a cancer drug repository.

Subd. 7. **Handling fees.** A cancer drug repository may charge the individual receiving a drug or supply a handling fee of no more than 250 percent of the medical assistance program dispensing fee for each cancer drug or supply dispensed or administered.

Subd. 8. **Distribution of donated cancer drugs and supplies.** (a) Cancer drug repositories may distribute drugs and supplies donated under the cancer drug repository program to other repositories if requested by a participating repository.

(b) A cancer drug repository that has elected not to dispense donated drugs or supplies shall distribute any donated drugs and supplies to a participating repository upon request of the repository.

(c) If a cancer drug repository distributes drugs or supplies under paragraph (a) or (b), the repository shall complete a cancer drug repository donor form provided by the board. The completed form and a copy of the donor form that was completed by the original donor under subdivision 5 shall be provided to the fully participating cancer drug repository at the time of distribution.

Subd. 9. **Resale of donated drugs or supplies.** Donated drugs and supplies may not be resold.

Subd. 10. **Record-keeping requirements.** (a) Cancer drug repository donor and recipient forms shall be maintained for at least five years.

(b) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 6 shall be maintained by the dispensing repository for at least five years. For each drug or supply destroyed, the record shall include the following information:

(1) the date of destruction;

(2) the name, strength, and quantity of the cancer drug destroyed;

(3) the name of the person or firm that destroyed the drug; and

(4) the source of the drugs or supplies destroyed.

Subd. 11. **Liability.** (a) The manufacturer of a drug or supply is not subject to criminal or civil liability for injury, death, or loss to a person or to property for causes of action described in clauses (1) and (2). A manufacturer is not liable for:

(1) the intentional or unintentional alteration of the drug or supply by a party not under the control of the manufacturer; or

(2) the failure of a party not under the control of the manufacturer to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(b) A medical facility or pharmacy participating in the program, a pharmacist dispensing a drug or supply pursuant to the program, a practitioner dispensing or administering a drug or supply pursuant to the program, or a donor of a cancer drug or supply as defined in subdivision 1 is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the cancer drug or supply is dispensed and no disciplinary action shall be taken against a pharmacist or practitioner so long as the drug or supply is donated, accepted, distributed, and dispensed according to the requirements of this section. This immunity does not apply if the act or omission involves reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the cancer drug or supply.

History: *1Sp2005 c 4 art 5 s 2; 2016 c 158 art 2 s 40*

RETURN OF UNUSED DRUGS

151.56 COUNTY RETURN OF UNUSED DRUGS OR MEDICAL DEVICES.

Notwithstanding Minnesota Rules, part 6800.2700, pharmacies may accept returns of and redispense unopened, unused drugs in board-approved unit dose packaging 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 correctional employee trained in the delivery and storage of medications 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; 2008 c 321 s 6*

AUTOMATED DRUG DISTRIBUTION

151.58 AUTOMATED DRUG DISTRIBUTION SYSTEMS.

Subdivision 1. **Scope.** This section applies only to the use of automated drug distribution systems located within the facilities specified in subdivision 2. Except as provided in this section, all applicable provisions of this chapter, chapter 152, and Minnesota Rules, chapter 6800, must be followed.

Subd. 2. **Definitions.** For purposes of this section only, the terms defined in this subdivision have the meanings given.

(a) "Automated drug distribution system" or "system" means a mechanical system approved by the board that performs operations or activities, other than compounding or administration, related to the storage, packaging, or dispensing of drugs, and collects, controls, and maintains all required transaction information and records.

(b) "Health care facility" means a nursing home licensed under section 144A.02; a housing with services establishment registered under section 144D.01, subdivision 4, in which a home provider licensed under chapter 144A is providing centralized storage of medications; a boarding care home licensed under sections 144.50 to 144.58 that is providing centralized storage of medications; or a Minnesota sex offender program facility operated by the Department of Human Services.

(c) "Managing pharmacy" means a pharmacy licensed by the board that controls and is responsible for the operation of an automated drug distribution system.

Subd. 3. **Authorization.** A pharmacy may use an automated drug distribution system to fill prescription drug orders for patients of a health care facility provided that the policies and procedures required by this section have been approved by the board. The automated drug distribution system may be located in a health care facility that is not at the same location as the managing pharmacy. When located within a health care facility, the system is considered to be an extension of the managing pharmacy.

Subd. 4. **Notification.** (a) At least 60 days prior to the initial use of an automated drug distribution system, the managing pharmacy must provide the board with written notification of the address at which the automated drug distribution system will be located, the manufacturer and model of the automated drug distribution system, and written policies and procedures that govern the operation of the system. The policies and procedures must address the requirements of subdivision 5 and the rules of the board. If the managing pharmacy will be using a system identical to the one for which it has previously provided notification to the board, and will be using identical policies and procedures, it must notify the board of the address at which the automated drug distribution system will be located and the manufacturer and model of the automated drug distribution system at least seven days in advance of using the system.

(b) The managing pharmacy must notify the board whenever an automated drug distribution system is taken permanently out of service.

(c) The managing pharmacy must notify the board whenever an automated drug distribution system is replaced. It must also provide the board with new written policies and procedures, unless an identical system is used as the replacement, 60 days prior to the replacement of the system.

Subd. 5. **Operation of automated drug distribution systems.** (a) The managing pharmacy and the pharmacist in charge are responsible for the operation of an automated drug distribution system.

(b) Access to an automated drug distribution system must be limited to pharmacy and nonpharmacy personnel authorized to procure drugs from the system, except that field service technicians may access a system located in a health care facility for the purposes of servicing and maintaining it while being monitored either by the managing pharmacy, or a licensed nurse within the health care facility. In the case of an automated drug distribution system that is not physically located within a licensed pharmacy, access for the purpose of procuring drugs shall be limited to licensed nurses. Each person authorized to access the system must be assigned an individual specific access code. Alternatively, access to the system may be controlled through the use of biometric identification procedures. A policy specifying time access parameters, including time-outs, logoffs, and lockouts, must be in place.

(c) For the purposes of this section only, the requirements of section 151.215 are met if the following clauses are met:

(1) a pharmacist employed by and working at the managing pharmacy, or at a pharmacy that is acting as a central services pharmacy for the managing pharmacy, pursuant to Minnesota Rules, part 6800.4075, must review, interpret, and approve all prescription drug orders before any drug is distributed from the

system to be administered to a patient. A pharmacy technician may perform data entry of prescription drug orders provided that a pharmacist certifies the accuracy of the data entry before the drug can be released from the automated drug distribution system. A pharmacist employed by and working at the managing pharmacy must certify the accuracy of the filling of any cassettes, canisters, or other containers that contain drugs that will be loaded into the automated drug distribution system, unless the filled cassettes, canisters, or containers have been provided by a repackager registered with the United States Food and Drug Administration and licensed by the board as a manufacturer; and

(2) when the automated drug dispensing system is located and used within the managing pharmacy, a pharmacist must personally supervise and take responsibility for all packaging and labeling associated with the use of an automated drug distribution system.

(d) Access to drugs when a pharmacist has not reviewed and approved the prescription drug order is permitted only when a formal and written decision to allow such access is issued by the pharmacy and the therapeutics committee or its equivalent. The committee must specify the patient care circumstances in which such access is allowed, the drugs that can be accessed, and the staff that are allowed to access the drugs.

(e) In the case of an automated drug distribution system that does not utilize bar coding in the loading process, the loading of a system located in a health care facility may be performed by a pharmacy technician, so long as the activity is continuously supervised, through a two-way audiovisual system by a pharmacist on duty within the managing pharmacy. In the case of an automated drug distribution system that utilizes bar coding in the loading process, the loading of a system located in a health care facility may be performed by a pharmacy technician or a licensed nurse, provided that the managing pharmacy retains an electronic record of loading activities.

(f) The automated drug distribution system must be under the supervision of a pharmacist. The pharmacist is not required to be physically present at the site of the automated drug distribution system if the system is continuously monitored electronically by the managing pharmacy. A pharmacist on duty within a pharmacy licensed by the board must be continuously available to address any problems detected by the monitoring or to answer questions from the staff of the health care facility. The licensed pharmacy may be the managing pharmacy or a pharmacy which is acting as a central services pharmacy, pursuant to Minnesota Rules, part 6800.4075, for the managing pharmacy.

History: *2012 c 166 s 4; 2014 c 291 art 5 s 15-17; 2015 c 71 art 9 s 11,12*

PHARMACY AUDIT INTEGRITY PROGRAM

151.60 PHARMACY AUDIT INTEGRITY PROGRAM.

The pharmacy audit integrity program is established to provide standards for an audit of pharmacy records carried out by a pharmacy benefits manager or any entity that represents pharmacy benefits managers.

History: *2012 c 215 s 1*

151.61 DEFINITIONS.

Subdivision 1. **Scope.** For the purposes of sections 151.60 to 151.70, the following terms have the meanings given.

Subd. 2. **Entity.** "Entity" means a pharmacy benefits manager or any person or organization that represents these companies, groups, or organizations.

Subd. 3. **Pharmacy benefits manager or PBM.** "Pharmacy benefits manager" or "PBM" means a person, business, or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management.

Subd. 4. **Plan sponsor.** "Plan sponsor" means the employer in the case of an employee benefit plan established or maintained by a single employer, a group purchaser as defined in section 62J.03, subdivision 6, or the employee organization in the case of a plan established or maintained by an employee organization, an association, joint board trustees, a committee, or other similar group that establishes or maintains the plan.

History: *2012 c 215 s 2*

151.62 PHARMACY BENEFIT MANAGER CONTRACT.

An amendment to pharmacy audit terms in a contract between a PBM and a pharmacy must be disclosed to the pharmacy at least 60 days prior to the effective date of the proposed change.

History: *2012 c 215 s 3*

151.63 PROCEDURE AND PROCESS FOR CONDUCTING AND REPORTING AN AUDIT.

Subdivision 1. **Audit procedures.** Unless otherwise prohibited by federal requirements or regulations, any entity conducting a pharmacy audit must follow the following procedures.

(1) A pharmacy must be given notice 14 days before an initial on-site audit is conducted.

(2) An audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist.

(3) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies.

Subd. 2. **Audit process.** Unless otherwise prohibited by federal requirements or regulations, for any entity conducting a pharmacy audit the following audit items apply.

(1) The period covered by the audit may not exceed 24 months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law.

(2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size must be appropriate for a statistically reliable sample. Notwithstanding section 151.69, the auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit.

(3) An on-site audit may not take place during the first five business days of the month unless consented to by the pharmacy.

(4) Auditors may not enter the pharmacy area unless escorted where patient-specific information is available and to the extent possible must be out of sight and hearing range of the pharmacy customers.

(5) Any recoupment will not be deducted against future remittances until after the appeals process and both parties have received the results of the final audit.

(6) A PBM may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:

(i) additional information is required in the provider manual; or

(ii) the information is required by the Food and Drug Administration (FDA); or

(iii) the information is required by the drug manufacturer's product safety program; and

(iv) the information in clause (i), (ii), or (iii) is not readily available for the auditor at the time of the audit.

(7) The auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(i) the plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(ii) a commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

History: *2012 c 215 s 4*

151.64 REQUIREMENTS FOR RECOUPMENT OR CHARGEBACK.

For recoupment or chargeback, the following criteria apply.

(1) Audit parameters must consider consumer-oriented parameters based on manufacturer listings.

(2) A pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the provider contract.

(3) A finding of overpayment or underpayment must be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(4) The entity conducting the audit shall not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulations.

(5) Calculations of overpayments must not include dispensing fees unless a prescription was not actually dispensed, the prescriber denied authorization, the prescription dispensed was a medication error by the pharmacy, or the identified overpayment is solely based on an extra dispensing fee.

(6) An entity may not consider any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record as fraud, however such errors may be subject to recoupment.

(7) In the case of errors that have no actual financial harm to the patient or plan, the PBM must not assess any chargebacks. Errors that are a result of the pharmacy failing to comply with a formal corrective action plan may be subject to recovery.

(8) Interest may not accrue during the audit period for either party, beginning with the notice of the audit and ending with the final audit report.

History: *2012 c 215 s 5*

151.65 DOCUMENTATION.

(a) To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or records including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner or additional audit documentation parameters located in the provider manual.

(b) Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

History: *2012 c 215 s 6*

151.66 APPEALS PROCESS.

The entity conducting the audit must establish a written appeals process which must include appeals of preliminary reports and final reports.

History: *2012 c 215 s 7*

151.67 AUDIT INFORMATION AND REPORTS.

(a) A preliminary audit report must be delivered to the pharmacy within 60 days after the conclusion of the audit.

(b) A pharmacy must be allowed at least 45 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the pharmacy within 120 days after receipt of the preliminary audit report or final appeal, whichever is later.

(d) An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within 45 days after the appeals process has been exhausted and the final audit report has been issued.

History: *2012 c 215 s 8*

151.68 DISCLOSURES TO PLAN SPONSOR.

Where contractually required, an auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any recouped money shall be returned to the plan sponsor.

History: *2012 c 215 s 9*

151.69 APPLICABILITY OF OTHER LAWS AND REGULATIONS.

Sections 151.62 to 151.67 do not apply to any investigative audit that involves suspected fraud, willful misrepresentation, abuse, or any audit completed by Minnesota health care programs.

History: *2012 c 215 s 10*

151.70 VIOLATIONS.

Violations of sections 151.62 to 151.68 may be grounds for action, but are not deemed misdemeanors as described in section 151.29.

History: *2012 c 215 s 11*

MAXIMUM ALLOWABLE COST PRICING

151.71 MAXIMUM ALLOWABLE COST PRICING.

Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions apply.

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

(c) "Pharmacy benefit manager" means an entity doing business in this state that contracts to administer or manage prescription drug benefits on behalf of any health plan company that provides prescription drug benefits to residents of this state.

Subd. 2. **Pharmacy benefit manager contracts with pharmacies; maximum allowable cost pricing.** (a) In each contract between a pharmacy benefit manager and a pharmacy, the pharmacy shall be given the right to obtain from the pharmacy benefit manager a current list of the sources used to determine maximum allowable cost pricing. The pharmacy benefit manager shall update the pricing information at least every seven business days and provide a means by which contracted pharmacies may promptly review current prices in an electronic, print, or telephonic format within one business day at no cost to the pharmacy. A pharmacy benefit manager shall maintain a procedure to eliminate products from the list of drugs subject to maximum allowable cost pricing in a timely manner in order to remain consistent with changes in the marketplace.

(b) In order to place a prescription drug on a maximum allowable cost list, a pharmacy benefit manager shall ensure that the drug is generally available for purchase by pharmacies in this state from a national or regional wholesaler and is not obsolete.

(c) Each contract between a pharmacy benefit manager and a pharmacy must include a process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing that includes:

(1) a 15-business day limit on the right to appeal following the initial claim;

(2) a requirement that the appeal be investigated and resolved within seven business days after the appeal is received; and

(3) a requirement that a pharmacy benefit manager provide a reason for any appeal denial and identify the national drug code of a drug that may be purchased by the pharmacy at a price at or below the maximum allowable cost price as determined by the pharmacy benefit manager.

(d) If an appeal is upheld, the pharmacy benefit manager shall make an adjustment to the maximum allowable cost price no later than one business day after the date of determination. The pharmacy benefit manager shall make the price adjustment applicable to all similarly situated network pharmacy providers as defined by the plan sponsor.

History: *2014 c 291 art 2 s 2*